

# MANUFACTURER'S DECLARATION

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*<sup>1</sup>
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

|                                                 |                                                   |
|-------------------------------------------------|---------------------------------------------------|
| Manufacturer name                               | B. Braun Melsungen AG                             |
| Manufacturer address and contact details        | Carl-Braun Straße 1<br>34212 Melsungen<br>GERMANY |
| Single Registration Number (SRN) (if available) | DE-MF-000000201                                   |

|                                                       |     |
|-------------------------------------------------------|-----|
| Authorised Representative name (if applicable)        | N/A |
| Authorised Representative address and contact details | N/A |
| Single Registration Number (SRN) (if available)       | N/A |

<sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

|                                                                                                                       |                                                                                 |                                                           |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------------------|
| Notified body name (if applicable)                                                                                    | TÜV SÜD Product Service GmbH                                                    | <input checked="" type="checkbox"/> See attached schedule |
| Notified body number (if applicable)                                                                                  | 0123                                                                            | <input checked="" type="checkbox"/> See attached schedule |
| Directive Certificate number(s) to which this confirmation is made (if applicable)                                    | (1) G1 012974 0607; (2) G1 019717 0032; (3) G1 022239 0080; (4) G2S 012974 0457 | <input checked="" type="checkbox"/> See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | (1) 2024-05-26; (2) 2024-05-26; (3) 2024-05-26; (4) 2024-05-26                  | <input checked="" type="checkbox"/> See attached schedule |
| End date of extended validity/transition period                                                                       | 2028-12-31                                                                      | <input checked="" type="checkbox"/> See attached schedule |

**We, as the manufacturer declare under our sole responsibility:**

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>2</sup>
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above or in the attached schedule
- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

*Choose applicable statements:*

- ☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second

<sup>2</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

*Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- ☒ Expired/expires *after* 20 March 2023:

*Choose one applicable statement:*

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

### ➤ Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

### ➤ Quality Management System (QMS)

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

### ➤ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

|                   | Quality Management                                                                                                                          | Regulatory Affairs                                                                                   |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Full Company Name | <b>B. Braun Melsungen AG</b>                                                                                                                | <b>B. Braun Melsungen AG</b>                                                                         |
| Location & Date   | <b>Melsungen, 2024-04-15</b>                                                                                                                | <b>Melsungen, 2024-04-15</b>                                                                         |
| Signature         | <b>See electronic signature</b>                                                                                                             | <b>See electronic signature</b>                                                                      |
| Print Name        | <b>(1) Thomas Brand; (2) Mareike Arico; (3) Dr. Frank Ritz</b>                                                                              | <b>(4) Dr. Stefan Seidel; (5) Malte Loh; (6) Dr. Joachim Buenger</b>                                 |
| Title             | <b>(1) Vice President Quality Management for non-active Medical Devices; (2) Head of Quality Management Active Medical Devices/ Head of</b> | <b>(4) Head of Regulatory Affairs CoE Infusion &amp; Pain Therapy; (5) Senior Manager Regulatory</b> |



|                                  |                                                                                                 |                                                                 |
|----------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
|                                  | <b>Regulatory Affairs CoE AIS; (3)<br/>Vice President QM Pharma;<br/>Hospital Care Division</b> | <b>Affairs; (6) Director Template &amp;<br/>Submission Mgmt</b> |
| Contact Details (at least email) | <b>BBMAG-HC@bbraun.com</b>                                                                      | <b>BBMAG-HC@bbraun.com</b>                                      |
| Version of document              | <b>Version 1.0</b>                                                                              |                                                                 |

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 -  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Perfusor® compactplus                                                                                                   | 8717030                                | 4039239000000038ZM                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® compactplus                                                                                                  | 8717050                                | 40392390000005352B                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| OnlineSuite                                                                                                             | 876100                                 | 40392390000005552H                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Spaceplus Perfusor®                                                                                                     | 8719030                                | 40392390000007562V                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Spaceplus Infusomat®                                                                                                    | 8719050                                | 40392390000007552T                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® compactplus P                                                                                                | 8717070                                | 40392390000007492Y                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Sangofix® Air                                                                                                           | 4116011F                               | 4039239000000039ZP                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnifix® Lock                                                                                                           | 4617006                                | 4039239000000044ZG                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnican fine                                                                                                            | 932M04SE                               | 403923900000018743B                  | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnican fine                                                                                                            | 931M08SE                               |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 600 V                                                                                                        | 5523606                                | 40392390000007973B                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Drug Library Manager Spaceplus                                                                                          | 876203                                 | 403923900000169539                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Drug Library Manager Spaceplus                                                                                          | 876209                                 | 403923900000169539                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| GLYCINE 1,5 % B. BRAUN                                                                                                  | FR29914                                | 403923900000249638                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| GLYCINE 1,5 % B. BRAUN                                                                                                  | FREU914                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| GLYCINE 1,5 % B. BRAUN                                                                                                  | FREU934                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| GLYCINE 1,5 % B. BRAUN                                                                                                  | FREU954                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| GLYCINE 1,5 % B. BRAUN                                                                                                  | FREU974                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | FREU850                                | 403923900000250128                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | FREU910                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | FREU930                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | FREU950                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | FREU970                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570100                                | 40392390000026312N                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3637006                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 0069414E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3521360                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570120                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570130                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570140                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 0066570E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3521370                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570150                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570160                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570170                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 0066569E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570110                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vitulia                                                                                                                 | 450268                                 | 40392390000025022A                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Vitulia                                                                                                                 | 450272                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570300                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570301                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570310                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570330                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 391858                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570350                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570360                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570340                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3637010                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 391859                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570370                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570380                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570390                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 391860                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570410                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570420                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570460                                | 40392390000026302L                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570470                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| NaCl 0,9 % B. BRAUN                                                                                                     | 3570480                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | FREU864                                | 40392390000025062J                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| RINGER B. BRAUN                                                                                                         | FREU924                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | FREU920                              |
| RINGER B. BRAUN                                                                                                         | FREU944                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | FREU964                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | FREU984                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | 3570000                                | 40392390000026342U                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| RINGER B. BRAUN                                                                                                         | 3570010                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | 3570020                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | 3570030                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | 3570040                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | 3570050                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| RINGER B. BRAUN                                                                                                         | 3570060                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| RINGER B. BRAUN                                                                                                         | 3570611                                | 40392390000026322Q                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 3570490                              |
| RINGER B. BRAUN                                                                                                         | 3570610                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 3570500                              |
| RINGER B. BRAUN                                                                                                         | 3570614                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 3570510                              |
| RINGER B. BRAUN                                                                                                         | 3570612                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 3570520                              |
| RINGER B. BRAUN                                                                                                         | 3570613                                | 40392390000026332S                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 3570530                              |
| Aqua B. Braun                                                                                                           | FREU812                                | 40392390000024973A                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Aqua B. Braun                                                                                                           | FREU852                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | FREU912                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | FREU932                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 387872                                 | 40392390000026272X                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Aqua B. Braun                                                                                                           | 387873                                 |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Aqua B. Braun                                                                                                           | 387874                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 442464                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 442465                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 442466                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterile Water for Irrigation                                                                                            | 3637011                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 3521380                                | 403923900000262933                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Aqua B. Braun                                                                                                           | 3521390                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 3553949                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 3553957                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 0065729E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 0066571E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 0069415E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 0082423E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Aqua B. Braun                                                                                                           | 0082479E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterile Water for Irrigation                                                                                            | 3637007                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Perifix® Catheter Connector                                                                                             | 4513800                                | 403923900000238732                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Perifix® Catheter Connector                                                                                             | 4513801                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Perifix® Catheter Connector NRFit                                                                                       | 4513800N-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Perifix® Catheter Connector NRFit                                                                                       | 4513801N-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space                                                                                                        | 8713050                                | 40392390000007462S                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Infusomat® Space P                                                                                                      | 8713070                                | 40392390000007472U                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Perfusor® Space                                                                                                         | 8713030                                | 40392390000007482W                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Enteroport® plus                                                                                                        | 8710355                                | 40392390000007452Q                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700200                                | 40392390000008622V                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700200-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700210                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700310                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700310-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700310CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 8250414SP                              | 40392390000007832Y                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 8250817SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 8250820SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 8250917SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 8250920SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Cyto-Set® Infusomat® Space                                                                                              | 835414SP                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 835817SP                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 835820SP                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 835917SP                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® Space                                                                                              | 835920SP                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700420                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700430                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700440                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700450                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700460                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700470                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700480                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Infusomat® plus                                                                                               | 8700490                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Line                                                                                                          | A2581NF                                | 403923900000078432                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Cyto-Set® Line                                                                                                          | A2582NF                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Cyto-Set® Mix                                                                                                           | A2900N                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Mix                                                                                                           | A2903N                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Mix                                                                                                           | A2906N                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Mix                                                                                                           | A2907N                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cyto-Set® Mix                                                                                                           | A2908N                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894251                                | 4039239000008602R                    | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Stimuplex® A                                                                                                            | 4894539                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894367                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894502                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894375                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894260                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894278                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894278NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894375NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894260NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894367NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894539NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894502NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® A                                                                                                            | 4894251 NR                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 60-12                                                                                                   | 4540002                                | 40392390000023452J                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Easypump® II LT 60-12                                                                                                   | 4540002-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 60-12                                                                                                   | 4540002-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 500-12.5                                                                                                | 4540003                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 500-12.5                                                                                                | 4540003-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 500-12.5                                                                                                | 4540003-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 80-16                                                                                                   | 4540004                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Easypump® II LT 80-16                                                                                                   | 4540004-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 80-16                                                                                                   | 4540004-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 125-25                                                                                                  | 4540006                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 125-25                                                                                                  | 4540006-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 125-25                                                                                                  | 4540006-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-27                                                                                                  | 4540008                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-27                                                                                                  | 4540008-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-27                                                                                                  | 4540008-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 60-30                                                                                                   | 4540010                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 60-30                                                                                                   | 4540010-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 60-30                                                                                                   | 4540010-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 120-30                                                                                                  | 4540012                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 120-30                                                                                                  | 4540012-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 120-30                                                                                                  | 4540012-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-40                                                                                                  | 4540014                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-40                                                                                                  | 4540014-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-40                                                                                                  | 4540014-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 100-50                                                                                                  | 4540016                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 100-50                                                                                                  | 4540016-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 100-50                                                                                                  | 4540016-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-54                                                                                                  | 4540018                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Easypump® II LT 270-54                                                                                                  | 4540018-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-54                                                                                                  | 4540018-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-80                                                                                                  | 4540022                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-80                                                                                                  | 4540022-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-80                                                                                                  | 4540022-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-68                                                                                                  | 4540026                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-68                                                                                                  | 4540026-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-68                                                                                                  | 4540026-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-100                                                                                                 | 4540028                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-100                                                                                                 | 4540028-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 400-100                                                                                                 | 4540028-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-135                                                                                                 | 4540032                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-135                                                                                                 | 4540032-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II LT 270-135                                                                                                 | 4540032-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-0,5                                                                                                 | 4540040                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-0,5                                                                                                 | 4540040-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-0,5                                                                                                 | 4540040-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-0,5                                                                                                 | 4540042                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-0,5                                                                                                 | 4540042-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-0,5                                                                                                 | 4540042-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 50-1                                                                                                    | 4540044                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Easypump® II ST 50-1                                                                                                    | 4540044-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 50-1                                                                                                    | 4540044-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-1                                                                                                   | 4540046                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-1                                                                                                   | 4540046-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-1                                                                                                   | 4540046-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-1                                                                                                   | 4540048                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump®II ST 250-1                                                                                                    | 4540048-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-1                                                                                                   | 4540048-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-1,5                                                                                                 | 4540050                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-1,5                                                                                                 | 4540050-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 250-1,5                                                                                                 | 4540050-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 400-2                                                                                                   | 4540052                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 400-2                                                                                                   | 4540052-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 400-2                                                                                                   | 4540052-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 500-2                                                                                                   | 4540054                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 500-2                                                                                                   | 4540054-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 500-2                                                                                                   | 4540054-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-2                                                                                                   | 4540056                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 100-2                                                                                                   | 4540056-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Easypump® II ST 100-2                                                                                                   | 4540056-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 400-4                                                                                                   | 4540058                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 400-4                                                                                                   | 4540058-07                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Easypump® II ST 400-4                                                                                                   | 4540058-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Spinal Introducer                                                                                                       | 4505000-13                             | 403923900000085836                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 4505000                              |
| Spinal Introducer                                                                                                       | 4500059-13                             |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4500059                              |
| Contiplex® S 360                                                                                                        | 4898650CN                              | 40392390000008542W                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Contiplex® S 360                                                                                                        | 4898610CN                              |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S 360                                                                                                        | 4898615CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S Ultra 360®                                                                                                 | 4898650-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S Ultra 360®                                                                                                 | 4898610-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S Ultra 360®                                                                                                 | 4898615-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S Ultra 360®                                                                                                 | 4898650-27                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S Ultra 360®                                                                                                 | 4898610-27                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S Ultra 360®                                                                                                 | 4898615-27                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Perifix® Filter                                                                                                         | 4515501                                | 403923900000238834                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Perifix® Filter NRFit                                                                                                   | 4515501N-01                            |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Contiplex® S Ultra 360® NRFit®                                                                                          | 4898650NR-27                           | 40392390000008542W                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Contiplex® S Ultra 360® NRFit®                                                                                          | 4898610NR-27                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® S Ultra 360® NRFit®                                                                                          | 4898615NR-27                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360® NRFit®                                                                                      | 4898704NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360® NRFit®                                                                                      | 4898705NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360® NRFit®                                                                                      | 4898710NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360® NRFit®                                                                                      | 4898715NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898704-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898705-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898710-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898715-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898704-27                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898705-27                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898710-27                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Contiplex® Tuohy Ultra 360®                                                                                             | 4898715-27                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4099117                                | 40392390000007582Z                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Discofix®                                                                                                               | 4095111                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4095120                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4095146                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4095111IN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 409511CN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 409512CN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 16466                                  |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4098102                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 409810CN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4098218                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 409821CN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4098501                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4098234                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4098080                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4055150                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4055145                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4055146                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4055149                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4055147                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4055148                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Discofix®                                                                                                               | 4099010                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix®                                                                                                               | 4095210                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 15809                                |
| Nutritub® ENFit® intestinal                                                                                             | 9246605                                | 40392390000029463J                   | G1 019717 0032<br><br>NB0123<br><br>B. Braun Avitum Italy S.p.A.                   | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 9246584                              |
| Nutritub® ENFit® intestinal                                                                                             | 9246604                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246586                              |
| Nutritub® ENFit® intestinal                                                                                             | 9246604                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246576                              |
| Nutritub® ENFit® intestinal                                                                                             | 9246604                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246578                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246603                                | 40392390000008172Q                   | G1 019717 0032<br><br>NB0123<br><br>B. Braun Avitum Italy S.p.A.                   | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 9246519                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246602                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246518                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246601                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246516                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246600                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246550                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246599                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246515                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246598                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246592                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246597                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246514                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246597                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246513                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246597                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246541                              |
| Nutritub® Gastral Basic ENFit®                                                                                          | 9246597                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246543                              |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable)     |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|------------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                          |
| Nutritub®<br>Gastral Basic<br>ENFit®                                                                                    | 9246596                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246512                                  |
| Nutritub®<br>Gastral Basic<br>ENFit®                                                                                    | 9246595                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246517<br>9246525<br>9246533<br>9246535 |
| Nutritub®<br>Gastral Basic<br>ENFit®                                                                                    | 9246594                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246509<br>9246511                       |
| Nutritub®<br>Gastral Basic<br>ENFit®                                                                                    | 9246593                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 9246508                                  |
| Infusomat®<br>Space Line                                                                                                | 8250832SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8250833SP                                |
| Infusomat®<br>Space Line                                                                                                | 8250834SP                              |                                      | NB0123                                                                             |                                                                                                                           | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 8250835SP                                |
| IN-Stopper                                                                                                              | 4238010                                | 40392390000028583L                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                      |
| IN-Stopper                                                                                                              | 4238011                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                      |
| Combi-Stopper                                                                                                           | 4495101                                | 40392390000008112C                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                      |
| Combi-Stopper                                                                                                           | 4495152                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                      |
| Combifix Adapter                                                                                                        | 5206634                                | 40392390000008122E                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                      |
| Combifix Adapter                                                                                                        | 5206642                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                      |
| Original Perfusor® Line                                                                                                 | 87229910                               | 40392390000008702U                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                      |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
|                                                                                                                         |                                        |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Pleurofix® No. 1                                                                                                        | 4461002                                | 40392390000007902V                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Pleurofix® No. 2                                                                                                        | 4461037                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Seldinger Introducer Needle                                                                                             | 4206096                                | 40392390000007442N                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Seldinger Introducer Needle                                                                                             | 4206100                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® 40 Duo                                                                                                          | 9166432C                               | 4039239000000121823                  | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Injekt® 40 Duo                                                                                                          | 9166432V                               |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251127-01                             | 40392390000007652W                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251127-03                             |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251127-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251127IN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251127JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251128-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251128-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251128-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251128IN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251128JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251129-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251129-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety®<br>3                                                                                                   | 4251129-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251129JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251130-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251130-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251130-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251130IN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251130JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251131-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251131-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251131-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251131JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251132-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251132-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251132-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251132IN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251133-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251133-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251133-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251134-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251134-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®<br>3                                                                                                   | 4251134-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety® 3                                                                                                      | 4251135-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251135-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251135-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251136-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251136-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251136-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251137-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251137-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251137-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® 3                                                                                                      | 4251144-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Infusomat® Space Line                                                                                                   | 8700036SP                              | 403923900000086737                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700435SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8701148SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8270066SP-01                           | 403923900000086635                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 8270066SP                            |
| Infusomat® Space Line                                                                                                   | 8270066SP-26                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700350-01                             | 403923900000086533                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700350-26                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Enteroport® ENFit® Set                                                                                                  |                                        | 4039239000000263732                  | G1 019717 0032                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 8721748                              |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
|                                                                                                                         | 8721739                                |                                      | NB0123<br>B. Braun Avitum Italy S.p.A.                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721749                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721750                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721688                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721726                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721734                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721735                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721736                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721737                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721742                              |
| Enteroport® ENFit® Set                                                                                                  | 8721738                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721744                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721745                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721746                              |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8721747                              |
| Double Spike Adaptor                                                                                                    | 4054032                                | 40392390000007883A                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Extension Line, Type: Alargadera                                                                                        | 4094603                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| In-line injection tubing                                                                                                | 4247116                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| LS-3 Connector                                                                                                          | 4053753                                | 403923900000078738                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| LS-2 Connector                                                                                                          | 4097122                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| LS-4 Connector                                                                                                          | 4097149                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| LS-5 Connector                                                                                                          | 4097157                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original-Kucher-extension tubing                                                                                        | 4887441                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| LS-2 Connector                                                                                                          | 9500103                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Cyto-Set®                                                                                                        | 8250266                                | 40392390000007832Y                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Cyto-Set®                                                                                                        | 8250366                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®                                                                                                        | 8250370                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250455SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250650SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250655SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250818SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250866SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250915SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250966SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250970SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat® Space                                                                                    | 8250980SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8250991SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8250992SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8250993SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8250994SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8251055SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8350866SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8350966SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8351655SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8352055SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set®<br>Infusomat®<br>Space                                                                                 | 8352074SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Cyto-Set® Infusomat® Space                                                                                       | 8352075SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182700                                | 403923900000078432                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182701                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182702                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182705                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182706                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182708                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Line                                                                                                   | 4182709                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Line                                                                                                   | 4182710                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Line                                                                                                   | 4182711                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182726                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182727                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Line                                                                                                   | 4182728                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182729                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Line                                                                                                   | 4182734                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4182817                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4188090                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4188091                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4188092                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Line                                                                                                   | 4188093                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Cyto-Set® Mix                                                                                                    | 4188925                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Mix                                                                                                    | 4188926                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Cyto-Set® Pump Adapter                                                                                           | 4182704                                | 403923900000078534                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Cyto-Set® Pump Adapter                                                                                                  | A1673SO                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Dosifix®                                                                                                                | 4037011                                | 40392390000008192U                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Dosifix®                                                                                                                | 4037012                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Dosifix®                                                                                                                | 4037013                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Dosifix®                                                                                                                | 4037032                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Dosifix®                                                                                                                | 4037031                                | 40392390000008202D                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
|                                                                                                                         |                                        |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Heidelberger Extension Tubing                                                                                           | 4033809                                | 403923900000078636                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Heidelberger Extension Tubing                                                                                           | 4034589                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Heidelberger Extension Tubing                                                                                           | 4038703                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Heidelberger Extension Tubing                                                                                           | 4055128                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Heidelberger Extension Tubing                                                                                           | 4055136                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line, Type: Heidelberger                                                                                      | 4097130                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line, Type: Heidelberger                                                                                      | 4097173                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Extension Line, Type: Heidelberger                                                                                      | 4097190                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line, Type: Heidelberger                                                                                      | 4097262                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line, Type: Heidelberger                                                                                      | 4097290                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line, Type: Heidelberger                                                                                      | 4097291                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line, Type: Heidelberger                                                                                      | 4097300                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line, Type: Heidelberger                                                                                      | 4097408                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan® Certo                                                                                                         | 4055764                                | 40392390000007612N                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Introcan® Certo                                                                                                         | 4251300                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan® Certo                                                                                                         | 4251318                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan® Certo                                                                                                         | 4251326                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan® Certo                                                                                                         | 4251334                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan® Certo                                                                                                         | 4251342                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan® Certo                                                                                                         | 4251350                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan® Certo                                                                                                         | 4251369                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®                                                                                                               | 4252071B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®                                                                                                               | 4252098B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®                                                                                                               | 4252110B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®                                                                                                               | 4252136B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®                                                                                                               | 4252160B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®                                                                                                               | 4252217B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan®                                                                                                               | 4252322B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W Certo                                                                                                       | 4253302                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W Certo                                                                                                       | 4253310                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W Certo                                                                                                       | 4253329                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W Certo                                                                                                       | 4253337                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W Certo                                                                                                       | 4253345                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W Certo                                                                                                       | 4253353                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W Certo                                                                                                       | 4253361                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W                                                                                                             | 4254074B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W                                                                                                             | 4254090B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W                                                                                                             | 4254112B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W                                                                                                             | 4254139B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W                                                                                                             | 4254171B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W                                                                                                             | 4254210B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan®-W                                                                                                             | 4254325B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C Safeflow                                                                                                    | 16494CCN                               | 40392390000007602L                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Discofix® C Safeflow                                                                                                    | 16495CCN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C Safeflow                                                                                                    | 16501CCN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C Safeflow                                                                                                    | 16500CCN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C Safeflow                                                                                                    | 16540CCN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C Safeflow                                                                                                    | 16520CCN                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrapur®-Neonat                                                                                                        | 4099451                                | 40392390000008082P                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Intrapur®                                                                                                               | 4093216                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterifix®                                                                                                               | 4184637                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterifix®                                                                                                               | 4099354                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterifix®                                                                                                               | 4099303                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterifix® Neonat                                                                                                        | 4099257                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrapur®                                                                                                               | 4099713                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4099753                              |
| Intrapur® Lipid                                                                                                         | 4099703                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4099850                              |
| Intrapur®                                                                                                               | 4183916                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrapur®                                                                                                               | 4099800                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrapur®                                                                                                               | 4099702                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrapur® Neonat Lipid                                                                                                  | 4099460                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16500CSF-1                             | 403923900000075933                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TUV SÜD Product Service GmbH (NB0123)                                               | TUV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Discofix® C                                                                                                             | 16540C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16494C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16801C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16494CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16800C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16504C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16501C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16760C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16495CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16613C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16609C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16503C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16605C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16751C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16502C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16612C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16740C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16551CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16497C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16610C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16540CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Discofix® C                                                                                                             | 16720C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16520CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16520C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16701C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16496C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16501CSF-1                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | RU16496C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | RU16495C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | CN16496C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | RU16494C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | EC16494C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | CN16494C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16611C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16608C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16600C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16501CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Pleuracan®                                                                                                              | 4462556                                | 40392390000007922Z                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Pleuracan® B                                                                                                            | 4462505                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Pleuracan® Back-Check Valve                                                                                             | 4462564                                | 403923900000079333                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Drainobag® Lock 600                                                                                                     | 5523682                                | 4039239000000281736                  | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Discofix® C                                                                                                             | 16700C                                 | 403923900000075933                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Discofix® C                                                                                                             | 16500C                                 |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16495C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16560CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16901C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16615C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Discofix® C                                                                                                             | 16560C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16494C-01                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16500CSF                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16551C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16900C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | BR16496C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Discofix® C                                                                                                             | 16614C                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Heidelberger Extension Tubing                                                                                           | 4052145                                | 40392390000026953G                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Heidelberger Extension Tubing                                                                                           | 4052197                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Heidelberger Extension Tubing                                                                                           | 4052197H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251601-01                             | 40392390000007632S                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Introcan Safety®                                                                                                        | 4251601-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251601-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251601JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251607-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251607-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251607-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251607JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4251614-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4251614-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4251614-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4251614JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety®                                                                                                        | 4251620-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251621-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251622-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251623-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251628-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251628-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251628-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251628JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251644-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251644-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251644-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251644JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251652-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251652-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251652-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251652JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251679-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251679-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251679-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251679JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251687-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety®                                                                                                        | 4251687-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251687-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251687JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251695-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251695-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251695-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251695JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251709-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251709-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251709-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251709JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251717-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251717-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251717-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251890-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251890-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4251890-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252500-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252500-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252500-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252519-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety®                                                                                                        | 4252519-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252519-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252520-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252527-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252527-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252535-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252535-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252535-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252543-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252551-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252551-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252551-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252560-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252560-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252560-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252578-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252578-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252578-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252586-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252586-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252594-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety®                                                                                                        | 4252594-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®                                                                                                        | 4252594-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253523-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253523-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253523-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253523JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253540-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253540-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253540-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253540JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253566-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253566-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253566-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253566JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253574-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253574-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253574-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253574JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253590-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253590-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety®-W                                                                                                      | 4253590-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety® W                                                                                                      | 4253604-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253604-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253604-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253604JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253612-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253612-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253612-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253639-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253639-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253639JP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4253639-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254503-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254503-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254503-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254511-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254511-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254511-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254538-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254538-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254538-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254546-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Introcan Safety® W                                                                                                      | 4254546-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254554-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254554-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254554-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254562-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254562-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254562-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254570-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254570-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254570-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254597-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254597-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Introcan Safety® W                                                                                                      | 4254597-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183913                                | 40392390000008082P                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183925                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183926                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183927                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183948                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183949                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4184004                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4184006                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Intrapur®                                                                                                        | 4184007                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4184008                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4098725                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4081002                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Sterifix® Neonat                                                                                                 | 4099265                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4187822                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4184001                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183255                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183245                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4183240                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4180351                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrapur®                                                                                                        | 4180350                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188960                                | 403923900000075933                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188959                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188957                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188105                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188071                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187954                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187826                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187202                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Discofix® C                                                                                                      | 4187199                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187032                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184963                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184491                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184246                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184030                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184022                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182635                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4181234                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180965                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4086481                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4085230                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4085213                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187203                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182308                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187527                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180437                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4183088                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4088698                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4084792                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4085300SF                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Discofix® C                                                                                                      | 4085086                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4181027                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184005                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187291                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4183312                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4185366                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4185927                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188188                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4086482                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184327                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180439                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180306                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182944                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4083255                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187911                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187823                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187878                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4085168                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4189821                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188958                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187213                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Discofix® C                                                                                                      | 4187880                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4083254                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4189847                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188198                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4183510                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187033                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188072                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4183787                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180678                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180679                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187879                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4185928                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4086879                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188047                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4189839                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4183852                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4185985                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4085450SF                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4089464                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182737                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180300                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Discofix® C                                                                                                      | 4183777                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4185972                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184521                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182652                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184483                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4087930                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184817                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187391                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182720                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4185821N                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4085434SF                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188225                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4186580                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4186579                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4085500SF                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4181778                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180459                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4188510                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180438                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4086945                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187898                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Discofix® C                                                                                                      | 4185021                                | 40392390000007622Q                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187529                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4088520                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4181028                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182638                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4088699                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180120                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180677                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182633                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182639                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187838                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4084510                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182651                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187834                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4180445                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4083777                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4187308                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4184424                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Discofix® C                                                                                                      | 4182182                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Braunüle®                                                                                                      | 4268091B                               | 40392390000007622Q                   | NB0123                                                                             | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Vasofix® Braunüle®                                                                                                      | 4268113B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Vasofix® Braunüle®                                                                                                      | 4268130B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Braunüle®                                                                                                      | 4268156B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Braunüle®                                                                                                      | 4268172B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Braunüle®                                                                                                      | 4268210B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Braunüle®                                                                                                      | 4268334B                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269071                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269098                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269110                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269136                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269152                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269179                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269217                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269225                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Certo                                                                                                          | 4269330                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line                                                                                                          | 4051807                                | 40392390000007893C                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Extension Line                                                                                                          | 4054393                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | NB0123                               |
| Extension Line                                                                                                          | 4054394                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Extension Line                                                                                                          | 4055137                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Extension Line                                                                                                          | 4055138                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Extension Line                                                                                                          | 4055139                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Extension Line                                                                                                          | 4055140                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Extension Line                                                                                                   | 4090144                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Spiral Line                                                                                                      | 4090365                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Spiral Line                                                                                                      | 4090373                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4090381                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4090383                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4090390                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4090438                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4091621                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4091622                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4091660                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268091S-01                            | 40392390000007642U                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268091S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268113S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268113S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268130S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268130S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268156S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268156S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268172S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268172S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268210S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268210S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4268334S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Vasofix® Safety                                                                                                         | 4268334S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269071S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269071S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269071SIN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269071S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269098S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269098S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269098SIN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269098S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269110S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269110S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269110SIN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269110S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269136S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269136S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269136SIN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269136S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269152S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269152S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269152S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269179S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Vasofix® Safety                                                                                                         | 4269179S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269179SIN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269179S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269217S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269217S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269217S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269225S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269225S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269225S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269330S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269330S-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasofix® Safety                                                                                                         | 4269330S-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4091728                                | 40392390000007893C                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4091736                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4091740                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4091752                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4092539                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4092937                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4092945                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4092953                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4092961                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Spiral Line                                                                                                      | 4092970                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4093054                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093115                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093130                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093150                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093170                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093185                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093215                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093230                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093250                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093270                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093285                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4093402                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4093437                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093585                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093607                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093830                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093850                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093870                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4093885                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Extension Line                                                                                                   | 4095251                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4097531                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line                                                                                                          | 4097572                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4099362                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4185841                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Extension Line                                                                                                   | 4185842                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4187466                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4187467                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4187468                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4187469                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Spiral Line                                                                                                      | 4188080                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line                                                                                                          | 9500049                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line                                                                                                          | 9500057                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Extension Line                                                                                                          | 9500065                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat@plus Line SafeSet                                                                                             | 8700390                                | 40392390000014782X                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat@plus Line SafeSet                                                                                             | 8700391                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat@plus Line SafeSet                                                                                             | 8700392                                | 4039239000000259235                  | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Infusomat® Space Line SafeSet                                                                                           | 8700140SP                              | 40392390000014772V                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8700141SP                              |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8700142SP                              | 403923900000259133                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4060369L                               | 40392390000007812U                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4060407                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062158                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062158C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062182                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Air                                                                                                           | 4062955                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062957E                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062981L                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062982L                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062983L                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063000                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063001                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063003                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063004                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063004C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063004M                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Intrafix® SafeSet                                                                                                       | 4063005                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063006                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Basse Pression                                                                                               | 5524237                                | 403923900000281736                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Drainobag® Lock 300                                                                                                     | 5522390                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 150                                                                                                          | 5523753                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 150                                                                                                     | 5523761                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 150                                                                                                     | 55237611                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 400                                                                                                     | 5523602                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | U2000600                             |
| Drainobag® 600 V                                                                                                        | 5523605                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 600 V                                                                                                   | 5523648                                | 40392390000007973B                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Drainobag® Lock 600 V                                                                                                   | 5523649                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Basse Pression TL                                                                                            | 5524210                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 300 V                                                                                                        | 5522322                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 300 V                                                                                                   | 5522340                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 300 V                                                                                                   | 55223401                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 150 V                                                                                                        | 5523702                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 150 VL                                                                                                       | 5523710                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 150 V                                                                                                   | 5523729                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 150 VL                                                                                                  | 5523737                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 150 VL                                                                                                  | 55237371                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Drainobag® 400 V                                                                                                        | 5523601                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | U2000500                             |
| Drainobag® Lock 400 V                                                                                                   | 5523603                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | U2000700                             |
| Drainobag® Lock 600 K 10                                                                                                | 5523400                                | 40392390000028193A                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Drainobag® Lock 600 K 10                                                                                                | 5523401                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 600 K 12                                                                                                | 5523427                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 600 K 12                                                                                                | 5523428                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063144                                | 40392390000007812U                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4063148                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4063287                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4088549                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4110000                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4110010                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4180038                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4182001A                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4182002A                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4182097                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4182098                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Intrafix® Primeline                                                                                              | 4182111                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4182179                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4182409                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4183450                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4183455                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4183665                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4183791                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4184321                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4186097                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4186109                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4186110                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4186168                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4186320                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4186711                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Intrafix® Primeline                                                                                              | 4186950                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4186980                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4186981                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187005                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4187006                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187007                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187008                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4187009                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187010                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4187011                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4187113                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187172                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix®                                                                                                        | 4187176                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187334                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Intrafix® Primeline                                                                                              | 4187555                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187946                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4187989                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4188020                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188030                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188110                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188113                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188114                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188115                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188116                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188117                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® Primeline                                                                                              | 4187105                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188120                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188136                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Intrafix® SafeSet                                                                                                | 4188137                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188140                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188155                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188159                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188170                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188530                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188531                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188540                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188550                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4189109                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4189582                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix® SafeSet                                                                                                | 4188119                                | 40392390000014832Q                   | G2S 012974 0457<br>NB0123                                                          | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4062877                                |                                      | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Intrafix® SafeSet                                                                                                       | 4062878                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Intrafix® Primeline                                                                                                     | 4110001                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4110002                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Intrafix®                                                                                                        | 4186914                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Intrafix® Primeline                                                                                                     | 4060563                                | 40392390000014822N                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| SafeSet                                                                                                                 | 4063000A                               | 40392390000007822W                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| SafeSet                                                                                                                 | 4063001CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| SafeSet                                                                                                                 | 4063003CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| SafeSet                                                                                                                 | 4063004CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| SafeSet                                                                                                                 | 4063004SFCN                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| SafeSet                                                                                                                 | 4063005CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| SafeSet                                                                                                                 | 4063006CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700340CN                              | 40392390000008622V                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700330CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700240-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700280                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700300                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700340                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700250                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700240                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Infusomat® Plus Line SafeSet                                                                                            | 8700220                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700330                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700320                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4092930                                | 40392390000014802J                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183945                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183943                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183941                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183938                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723017CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722919                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723017                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722919-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723017-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723018                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183968                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4093000                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183937                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183942                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183947                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183930                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Original Perfusor® Line                                                                                          | 4183933                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183935                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183936                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700350CN                              | 403923900000086533                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700350-20                             |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700360                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700132SP                              | 40392390000008693B                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
|                                                                                                                         |                                        |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
|                                                                                                                         |                                        |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Infusomat® Space Line                                                                                                   | 8270074SP                              | 403923900000086635                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250908SP                              |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250902SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250900SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250077SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4182586SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4181557SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250958SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Infusomat® Plus Line                                                                                                    | 8700370CN                              | 40392390000008632X                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700400                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700370                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 9167641WE                              | 4039239000001006ZF                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnican® fine                                                                                                           | 9167650WE                              |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 9167684WE                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 9167820WE                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 929G12S-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 929G12S-41                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 929G12S-43                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G04S-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G04S-41                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G04S-43                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G04SCN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G04SCN1                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G06S-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G06S-41                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G06S-43                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G06S-AP                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G06SCN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G06SCN1                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G08S-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G08S-41                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G08S-43                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 931G08S-44                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G04S-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G04S-41                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G04S-43                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G04S-AP                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Omnican® fine                                                                                                           | 932G04SCN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G04SCN1                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G05SCN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G05SCN1                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G06S-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G06S-41                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G06S-43                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G06SCN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932G06SCN1                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932P04                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932P05                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® fine                                                                                                           | 932P06                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700270                                | 40392390000020742A                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700260-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Plus Line SafeSet                                                                                            | 8700260                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722865                                | 40392390000008722Y                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infusomat® Plus Line                                                                                                    | 8700410                                | 40392390000008642Z                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4182190SP                              | 403923900000086737                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4180639SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4180020SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Infusomat® Space Line                                                                                            | 8250918SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8251001SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8251002SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4182191SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4183900                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8270058SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8252658SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250358SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250903SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4182653SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4187897                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4184904SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4188063SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4180635SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Infusomat® Space Line                                                                                            | 4188166SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4189980SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4186524SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4189979SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4089340SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250905SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4183911                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4185489                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4187769SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8251284SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4185308SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8250904SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4186486SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700095SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700110SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Infusomat® Space Line                                                                                                   | 8270350SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8250710SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8250731SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700131SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8250719SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4183878SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4180633SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8250718SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8700098SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8701149SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8700130SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8700118SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8250720SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4183918                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4183910                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4187789SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Infusomat® Space Line                                                                                            | 4185976SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4181558SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4089391SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8270597SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8270358SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4187899                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4183189SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4186940SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700087SP-26                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700087SP-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8251005SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8251004SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8251003SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4183950SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4180631SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Infusomat® Space Line                                                                                            | 4183901                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4189981SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4187377                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4182189SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 8252659SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4185687                                | 40392390000008712W                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4085129                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 8250803                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183971                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183970                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8255504N                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8745919N                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722940                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723060CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8255253                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723024                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723023                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723026                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Original Perfusor® Line                                                                                                 | 8723025                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723021                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723020                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 8250782                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 8250847                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722941                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722960                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8250146                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723060                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4185595                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8272565                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8255067                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722960-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8255504NCN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722862-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723060-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722862                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722935                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8255172                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8255059                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4092933                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Original Perfusor® Line                                                                                          | 4092932                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4092931                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722935CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722870N                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722820                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8722935-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8255490                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4183969                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 0066088K                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 0066086H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Original Perfusor® Line                                                                                          | 4180441                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 0066087J                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 0009483H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4186850                                | 40392390000014792Z                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| ProSet Infusomat® Space Line                                                                                            | 4186842SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8700128SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8700127SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line                                                                                                   | 8250437SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Infusomat® Space Line SafeSet                                                                                           | 8250438SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| ProSet Infusomat® Space Line                                                                                            | 8252671SP                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4050192                                | 40392390000027342Z                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Sangofix®                                                                                                               | 4050192H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4050193                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4052013                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4052013H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4053710                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4053710H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4146492                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4034228                                | 4039239000000039ZP                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Sangofix® Air                                                                                                           | 4050151                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4051998                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4051998H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4052005                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4052005H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4052218H                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix® Air                                                                                                           | 4080187                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4100514                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4117301                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sangofix®                                                                                                               | 4117549                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Line                                                                                                 | 8723001                                | 40392390000027242W                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Infuvalve®                                                                                                              | 4094000N                               | 40392390000008102A                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Combi-Stopper                                                                                                           | 4495209                                | 40392390000008112C                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Combi-Stopper                                                                                                           | 4495101R                               |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Safeflow Extension Set                                                                                                  | 4097154N                               | 40392390000008152L                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Safeflow Extension Set                                                                                                  | 4097145N                               |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Safeflow Extension Set                                                                                                  | 4097154                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Safeflow                                                                                                                | 409110H                                | 40392390000008162N                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Safeflow                                                                                                                | 409100CN                               |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Safeflow                                                                                                                | 409101H                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Safeflow                                                                                                                | 409100H                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Safeflow Extension Set                                                                                                  | 4097148N                               | 403923900000027222S                  | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
|                                                                                                                         |                                        |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Omnican® 50                                                                                                             | 9151117S                               | 4039239000009362Z                    | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnican® 50                                                                                                             | 9151125S                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® 100                                                                                                            | 9151133S                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® 100                                                                                                            | 9151141S                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® 100                                                                                                            | 9151141SC                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® 20                                                                                                             | 9161619S                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® 40                                                                                                             | 9161627S                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® 40                                                                                                             | 9161627SC                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® 40                                                                                                             | 9161635S                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnican® F                                                                                                              | 9161502S                               | 40392390000093937                    | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| IBSA FSH/LH                                                                                                             | 9161530S                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Serofine™ needle                                                                                                        | 16441MS                                | 4039239000001007ZH                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Serofine™ needle                                                                                                        | 16443MS                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Serofine® needle                                                                                                        | 16441EMD                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| B. Braun Pen Needle                                                                                                     | 16441CA                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Pencylcap™                                                                                                              | P1400060                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Pencylcap™                                                                                                              | P1400061                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| B. Braun Pen Needle                                                                                                     | P1400062                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Pencylcap™                                                                                                              | U1244000                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Pencylcap®                                                                                                              | U1244100                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| B. Braun Pen Needle                                                                                                     | P1400062CA                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| B. Braun Pen needle                                                                                                     | U1244100CA                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Pen Needle B. Braun F-Pen DS                                                                                            | P1400075                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Serofine® needle                                                                                                        | 16443EMD                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Drainobag® Lock 600 K 14                                                                                                | 5523443                                | 40392390000028193A                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Drainobag® Lock 600 K 14                                                                                                | 5523444                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 600 K 16                                                                                                | 5523460                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Lock 600 K 16                                                                                                | 5523461                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 150 K 6                                                                                                      | 5523800                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 150 K 6                                                                                                      | 55238001                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 150 K 8                                                                                                      | 5523850                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® 150 K 8                                                                                                      | 55238501                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® 40 Duo                                                                                                         | 9161333V                               | 4039239000001217ZW                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnifix® 100 Duo                                                                                                        | 9161376C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® 100 Duo                                                                                                        | 9161376V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643011C                               | 403923900000077633                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643100V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643102C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643102V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643105V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643119C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643119V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643127C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643127V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Omnifix® Luer Duo                                                                                                       | 4643135C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643135V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix®-F Luer Duo                                                                                                     | 9161465V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Duo                                                                                                       | 4643161                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617022V                               | 403923900000077735                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617022V-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617029V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617053V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617053V-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617100CA                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617100V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617100V-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617207V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617207V-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617304F                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617509F                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617509F-03                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Luer Lock Solo                                                                                                 | 4617510F-06                            | 4039239000000207022                  | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670002S-01                            | 403923900000076936                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican® Safety Needle                                                                                                 | 4670005S-01                            |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670008S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670008SBR                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670012S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670016S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670020S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670022S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670025S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670027S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670028S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670030S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670032S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670035S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670035SBR                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670040S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670040SBR                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670042S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670045S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670045SBR                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670047S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670050S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican® Safety Needle                                                                                                 | 4670052S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670053S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670055S-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670055SBR                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 4650018                                | 403923900000076834                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Sterican®                                                                                                               | 4650034                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 4657500                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657519                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657527                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657543                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657624                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657640                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657667                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657675                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657683                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657705                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657799                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4657853                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4660021                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665112                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665120                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665317                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665406                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665457                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665465                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665503                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665511                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665600                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665635                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Sterican®                                                                                                               | 4665643                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 4665791                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 4667093                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 4667123                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 9180109                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 9180117                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 9186158                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 9186166                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 9186174                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican®                                                                                                               | 9186182                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt®-H Luer Duo                                                                                                      | 9166297                                | 40392390000007742X                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645022C                               | 40392390000007752Z                   | G1 012974 0607<br>NB0123                                                           | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645022UA                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645022V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645057C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645057UA                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645057V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645065C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645103C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645103UA                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645103V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645200C                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4645200UA                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Injekt® Luer Duo                                                                                                        | 4645200V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt® Luer Duo                                                                                                        | 4647220                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Injekt®-F Luer Duo                                                                                                      | 9166033V                               |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670030SBR                             | 403923900000076936                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Sterican® Safety Needle                                                                                                 | 4670053SBR                             |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4898323                                | 40392390000008522S                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Contiplex® D                                                                                                            | 4898325                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4898305                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4898308                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4898311                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4898335                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D NRFit®                                                                                                     | 4898305NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D NRFit®                                                                                                     | 4898335NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D NRFit®                                                                                                     | 4898311NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D NRFit®                                                                                                     | 4898323NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D NRFit®                                                                                                     | 4898325NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4895819NCN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4894235NCN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4894391NCN                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4898205                                | 40392390000008532U                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Contiplex® D                                                                                                            | 4898211                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® D                                                                                                            | 4898235                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® C                                                                                                            | 4898115                                | 403923900000085000                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Contiplex® C                                                                                                            | 4898130                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® C NRFit®                                                                                                     | 4898115NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Contiplex® C NRFit®                                                                                                     | 4898130NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892603-01                             | 40392390000008552Y                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892603CN                              |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360 NRFit®                                                                                                   | 4892603NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892605-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892605CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360 NRFit®                                                                                                   | 4892605NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892608-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892608CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360 NRFit®                                                                                                   | 4892608NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892610-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892610CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360 NRFit®                                                                                                   | 4892610NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892615-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360                                                                                                          | 4892615CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Ultraplex® 360 NRFit®                                                                                                   | 4892615NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892105                                | 40392390000008502N                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Stimuplex® D                                                                                                            | 4892105-23                             |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892105CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892105NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892108                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892108-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892108CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Stimuplex® D NRFit®                                                                                                     | 4892108NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892112                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892112-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892112CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892112NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892115                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892115-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892115NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892134                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892134-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892134NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892137                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892137-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892137NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892153                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892153-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892153NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892155                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892155-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892155NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892205                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892205-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892205NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892208                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D                                                                                                            | 4892208-23                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® D NRFit®                                                                                                     | 4892208NR                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892503-01                             | 40392390000008512Q                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Stimuplex® Ultra 360®                                                                                                   | 4892503-03                             |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892503-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892503-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® 360®                                                                                                         | 4892503CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360® NRFit®                                                                                            | 4892503NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892505-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892505-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892505-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892505-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® 360®                                                                                                         | 4892505CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360® NRFit®                                                                                            | 4892505NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892508-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892508-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892508-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892508-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® 360®                                                                                                         | 4892508CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360® NRFit®                                                                                            | 4892508NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892510-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892510-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892510-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Stimuplex® Ultra 360®                                                                                                   | 4892510-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® 360®                                                                                                         | 4892510CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360® NRFit®                                                                                            | 4892510NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892515-01                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892515-03                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892515-04                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360®                                                                                                   | 4892515-20                             |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® 360®                                                                                                         | 4892515CN                              |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Stimuplex® Ultra 360® NRFit®                                                                                            | 4892515NR-01                           |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Lock                                                                                                           | 4617003                                | 403923900000044ZG                    | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Omnifix® Lock                                                                                                           | 4617014                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Lock                                                                                                           | 4617021                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Omnifix® Lock                                                                                                           | 4617508F-01                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 20 ml                                                                                        | 8728615                                | 403923900000077939                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Original Perfusor® Syringe 20 ml                                                                                        | 8728615C                               |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 20 ml                                                                                        | 8728623                                | 40392390000029923R                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Original Perfusor® Syringe 20 ml                                                                                        | 8728623C                               |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728810F-04                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728810F-06                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8728810F                             |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728810F-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728844F-04                            | 403923900000077939                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728844F-06                            |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 8728844F                             |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728844F-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728852F-04                            | 40392390000029923R                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728852F-06                            |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728852F-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728861F-04                            | 403923900000207124                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728861F-06                            |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728861F-20                            |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Original Perfusor® Syringe 50 ml                                                                                        | 8728845F-01                            | 40392390000007802S                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
|                                                                                                                         |                                        |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Cystofix®                                                                                                               | 4450100                                | 40392390000009993R                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Cystofix®                                                                                                               | 4450120                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix®                                                                                                               | 4450130                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Cystofix®                                                                                                               | 4450150                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix®                                                                                                               | 4450160                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix®                                                                                                               | 4450170                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix®                                                                                                               | 4450180                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix®                                                                                                               | 4450200                                | 4039239000001000Z3                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Cystofix®                                                                                                               | 4450220                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix SG                                                                                                             | 4450410                                | 4039239000001002Z7                   | G1 022239 0080                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Cystofix SG                                                                                                             | 4450412                                |                                      | NB0123<br>B.BRAUN MEDICAL SAS                                                      |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix SG                                                                                                             | 4450414                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix SG                                                                                                             | 4450416                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450010                                | 4039239000001001Z5                   | G1 022239 0080                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Cystofix                                                                                                                | 4450012                                |                                      | NB0123<br>B.BRAUN MEDICAL SAS                                                      |                                                                                                                           | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450014                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450016                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450512                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450514                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450516                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450712                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450714                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450716                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450718                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Cystofix                                                                                                                | 4450720                                |                                      | N/A                                                                                |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Vasco® OP Powdered                                                                                                      | 6031510                                | 40392390000009272Y                   | G1 012974 0607                                                                     | 2024-05-26                                                                                                                | TUV SUD Product Service GmbH (NB0123)                                               | TUV SUD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | N/A                                  |
| Vasco® OP Powdered                                                                                                      | 6031525                                |                                      | NB0123                                                                             |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Powdered                                                                                                      | 6031532                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16  
Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Vasco® OP Powdered                                                                                                      | 6031546                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Powdered                                                                                                      | 6031553                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Powdered                                                                                                      | 6031564                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6080990                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6081002                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6081010                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6081029                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6081037                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6081045                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6081053                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Sensitive                                                                                                     | 6081060                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081199                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081200                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081218                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081226                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081234                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081242                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081259                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Underglove                                                                                                    | 6081267                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP eco                                                                                                           | 6081308                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP eco                                                                                                           | 6081316                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Vasco® OP eco                                                                                                           | 6081324                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP eco                                                                                                           | 6081332                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP eco                                                                                                           | 6081340                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP eco                                                                                                           | 6081359                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP eco                                                                                                           | 6081367                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP eco                                                                                                           | 6081375                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081409                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081417                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081425                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081433                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081441                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081450                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081468                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Grip                                                                                                          | 6081476                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Free                                                                                                          | 9208291                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Free                                                                                                          | 9208305                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Free                                                                                                          | 9208313                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Free                                                                                                          | 9208321                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Free                                                                                                          | 9208330                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Free                                                                                                          | 9208348                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Vasco® OP Free                                                                                                          | 9208356                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |

Effective

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 - Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) <sup>3</sup><br>(e.g., device name, family/group name device model or catalogue number) |                                        |                                      | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------|--------------------------------------|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------|--------------------------------------|
| Article name                                                                                                            | Article Number (under MDR application) | Basic UDI-DI (under MDR application) |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   |                                      |
| Vasco® OP Free                                                                                                          | 9208364                                |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | N/A                                  |
| Drainobag® Connection Tube Bayonet                                                                                      | 5524913                                | 40392390000008052H                   | G1 012974 0607<br><br>NB0123                                                       | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | U2170701                             |
| Filter Needle                                                                                                           | 415040                                 | 4039239000000290000                  | G2S 012974 0457<br><br>NB0123                                                      | 2024-05-26                                                                                                                | TÜV SÜD Product Service GmbH (NB0123)                                               | TÜV SÜD Product Service GmbH (NB0123)                                                              | 2028-12-31                                        | 4550404                              |
| Filter Hub                                                                                                              | 418021                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4551001                              |
| Filter Straw                                                                                                            | 415020                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4550200                              |
| Filter Straw                                                                                                            | 415021                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4550250                              |
| Sterifix® Filter Straw 4"                                                                                               | 339171                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4550200N                             |
| Sterifix® Filter Straw 1.75"                                                                                            | 339170                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4550250N                             |
| Sterifix® Filter Needle 1.5"                                                                                            | 339169                                 |                                      |                                                                                    |                                                                                                                           |                                                                                     |                                                                                                    |                                                   | 4550404N                             |

<sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Effective

Document History

| Version | Description of Change |
|---------|-----------------------|
| 1.0     | Initial version       |

B. Braun Meisungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 -  
Title: BBWAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10

Effective

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Voelske, Rebecca (voelrede)  
Title: Head of RA Product Mgmt. Inf. Therapy  
Date: Wednesday, 15 May 2024, 15:10 W. Europe Daylight Time  
Meaning: Document signed as Author

=====

UserName: Buenger, Joachim (buenjode)  
Title: Director Template & Submission Mgmt  
Date: Wednesday, 15 May 2024, 15:24 W. Europe Daylight Time  
Meaning: Approve Document

=====

UserName: Seidel, Stefan (seidstde)  
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Wednesday, 15 May 2024, 16:49 W. Europe Daylight Time  
Meaning: Approve Document

=====

UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Wednesday, 15 May 2024, 17:22 W. Europe Daylight Time  
Meaning: Approve Document

=====

UserName: Arico, Mareike (sommrde)  
Title: HC-QM - Head of QM active MD/ Head of Regulatory Affairs CoE AIS  
Date: Wednesday, 15 May 2024, 21:34 W. Europe Daylight Time  
Meaning: Approve Document

=====



Title: BBMAG\_LM\_confirmation letter\_Regulation EU 2023/607\_G10 Initiator: Anja Mai

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Loh, Malte (lohmatde)  
Title: HC-RA-DE08 Senior Manager Regulatory Affairs  
Date: Thursday, 16 May 2024, 07:36 W. Europe Daylight Time  
Meaning: Approve Document

=====

UserName: Ritz, Frank (ritzfrde)  
Title: HC-QM DE08 Head QM CoE Pharmaceuticals  
Date: Thursday, 16 May 2024, 08:19 W. Europe Daylight Time  
Meaning: Approve Document

=====

UserName: Meyer, Frank (meyefrde)  
Title: HC-QM-DE08 Vice President QM Applications Hospital Care  
Date: Thursday, 16 May 2024, 09:09 W. Europe Daylight Time  
Meaning: Final Release of the Document

=====