

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*¹
- 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 34212 Melsungen 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

¹ 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*²
- 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

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

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

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

Schedule of Devices

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

Identification of the device(s) ³ (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	403923900000038ZM	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus	8717050	40392390000005352B	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
OnlineSuite	876100	40392390000005552H	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Perfusor®	8719030	40392390000007562V	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Infusomat®	8719050	40392390000007552T	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus P	8717070	40392390000007492Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4116011F	403923900000039ZP	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617006	403923900000044ZG	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	932M04SE	403923900000018743B	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	931M08SE		NB0123					N/A
Drainobag® 600 V	5523606	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FR29914	403923900000249638	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000025022A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	3570470							N/A
NaCl 0,9 % B. BRAUN	3570480							N/A
RINGER B. BRAUN	FREU864	40392390000025062J	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	FREU924							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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	3570010							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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570530
Aqua B. Braun	FREU812	40392390000024973A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	387873							N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Enteroport® plus	8710355	40392390000007452Q	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200	40392390000008622V	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Line	A2582NF		NB0123					N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000085836	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	4505000
Spinal Introducer	4500059-13		NB0123					4500059
Contiplex® S 360	4898650CN	4039239000008542W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Filter NRFit	4515501N-01		NB0123					N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	4039239000008542W	G1 012974 0607 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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
Discifix®	4099117	40392390000007582Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discifix®	4095111							N/A
Discifix®	4095120							N/A
Discifix®	4095146							N/A
Discifix®	4095111IN							N/A
Discifix®	409511CN							N/A
Discifix®	409512CN							N/A
Discifix®	16466							N/A
Discifix®	4098102							N/A
Discifix®	409810CN							N/A
Discifix®	4098218							N/A
Discifix®	409821CN							N/A
Discifix®	4098501							N/A
Discifix®	4098234							N/A
Discifix®	4098080							N/A
Discifix®	4055150							N/A
Discifix®	4055145							N/A
Discifix®	4055146							N/A
Discifix®	4055149							N/A
Discifix®	4055147							N/A
Discifix®	4055148	N/A						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123 B. Braun Avitum Italy S.p.A.	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246584 9246586
Nutritub® ENFit® intestinal	9246604							9246576 9246578
Nutritub® Gastral Basic ENFit®	9246603	40392390000008172Q	G1 019717 0032 NB0123 B. Braun Avitum Italy S.p.A.	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246519
Nutritub® Gastral Basic ENFit®	9246602							9246518
Nutritub® Gastral Basic ENFit®	9246601							9246516 9246550
Nutritub® Gastral Basic ENFit®	9246600							9246515 9246592
Nutritub® Gastral Basic ENFit®	9246599							9246514
Nutritub® Gastral Basic ENFit®	9246598							9246513
Nutritub® Gastral Basic ENFit®	9246597							9246541 9246543

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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® Gastral Basic ENFit®	9246596							9246512
Nutritub® Gastral Basic ENFit®	9246595							9246517
								9246525
								9246533
								9246535
Nutritub® Gastral Basic ENFit®	9246594							9246509
Nutritub® Gastral Basic ENFit®	9246593							9246511
Infusomat® Space Line	8250832SP	40392390000086839	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8250833SP
Infusomat® Space Line	8250834SP		NB0123					8250835SP
IN-Stopper	4238010	40392390000028583L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
IN-Stopper	4238011		NB0123					N/A
Combi-Stopper	4495101	4039239000008112C	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495152		NB0123					N/A
Combifix Adapter	5206634	4039239000008122E	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combifix Adapter	5206642		NB0123					N/A
Original Perfusor® Line	87229910	4039239000008702U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	403923900000121823	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					

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	4251129-04							N/A
Introcan Safety® 3	4251129JP							N/A
Introcan Safety® 3	4251130-01							N/A
Introcan Safety® 3	4251130-03							N/A
Introcan Safety® 3	4251130-04							N/A
Introcan Safety® 3	4251130IN							N/A
Introcan Safety® 3	4251130JP							N/A
Introcan Safety® 3	4251131-01							N/A
Introcan Safety® 3	4251131-03							N/A
Introcan Safety® 3	4251131-04							N/A
Introcan Safety® 3	4251131JP							N/A
Introcan Safety® 3	4251132-01							N/A
Introcan Safety® 3	4251132-03							N/A
Introcan Safety® 3	4251132-04							N/A
Introcan Safety® 3	4251132IN							N/A
Introcan Safety® 3	4251133-01							N/A
Introcan Safety® 3	4251133-03							N/A
Introcan Safety® 3	4251133-04							N/A
Introcan Safety® 3	4251134-01							N/A
Introcan Safety® 3	4251134-03							N/A
Introcan Safety® 3	4251134-04							N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8270066SP
Infusomat® Space Line	8270066SP-26							N/A
Infusomat® Plus Line	8700350-01	403923900000086533	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-26							N/A
Enteroport® ENFit® Set		403923900000263732	G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8721748

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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	4039239000007883A	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, Type: Alargadera	4094603		NB0123					N/A
In-line injection tubing	4247116							N/A
LS-3 Connector	4053753	40392390000078738	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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® Infusomat® Space	8250455SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250650SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250655SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250818SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250866SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250915SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250966SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250970SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250980SP							N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	8250991SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250992SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250993SP							N/A
ProSet Cyto-Set® Infusomat® Space	8250994SP							N/A
ProSet Cyto-Set® Infusomat® Space	8251055SP							N/A
ProSet Cyto-Set® Infusomat® Space	8350866SP							N/A
ProSet Cyto-Set® Infusomat® Space	8350966SP							N/A
ProSet Cyto-Set® Infusomat® Space	8351655SP							N/A
ProSet Cyto-Set® Infusomat® Space	8352055SP							N/A
ProSet Cyto-Set® Infusomat® Space	8352074SP							N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set® Mix	4182701							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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberg Extension Tubing	4033809	403923900000078636	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberg Extension Tubing	4034589		NB0123					N/A
Heidelberg Extension Tubing	4038703		N/A					
Heidelberg Extension Tubing	4055128		N/A					
Heidelberg Extension Tubing	4055136		N/A					
Extension Line, Type: Heidelberg	4097130		N/A					
Extension Line, Type: Heidelberg	4097173		N/A					

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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: Heidelberg	4097190							N/A
Extension Line, Type: Heidelberg	4097262							N/A
Extension Line, Type: Heidelberg	4097290							N/A
Extension Line, Type: Heidelberg	4097291							N/A
Extension Line, Type: Heidelberg	4097300							N/A
Extension Line, Type: Heidelberg	4097408							N/A
Introcan® Certo	4055764							40392390000007612N
Introcan® Certo	4251300		NB0123					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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrapur®	4093216							N/A
Sterifix®	4184637							N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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
Discifix® C	16500CSF-1	403923900000075933	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discifix® C	16540C		NB0123					N/A
Discifix® C	16494C							N/A
Discifix® C	16801C							N/A
Discifix® C	16494CSF							N/A
Discifix® C	16800C							N/A
Discifix® C	16504C							N/A
Discifix® C	16501C							N/A
Discifix® C	16760C							N/A
Discifix® C	16495CSF							N/A
Discifix® C	16613C							N/A
Discifix® C	16609C							N/A
Discifix® C	16503C							N/A
Discifix® C	16605C							N/A
Discifix® C	16751C							N/A
Discifix® C	16502C							N/A
Discifix® C	16612C							N/A
Discifix® C	16740C							N/A
Discifix® C	16551CSF							N/A
Discifix® C	16497C							N/A
Discifix® C	16610C							N/A
Discifix® C	16540CSF	N/A						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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)						
Discifix® C	16720C	4039239000007922Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discifix® C	16520CSF							N/A
Discifix® C	16520C							N/A
Discifix® C	16701C							N/A
Discifix® C	16496C							N/A
Discifix® C	16501CSF-1							N/A
Discifix® C	RU16496C							N/A
Discifix® C	RU16495C							N/A
Discifix® C	CN16496C							N/A
Discifix® C	RU16494C							N/A
Discifix® C	EC16494C							N/A
Discifix® C	CN16494C							N/A
Discifix® C	16611C							N/A
Discifix® C	16608C							N/A
Discifix® C	16600C							N/A
Discifix® C	16501CSF	N/A						
Pleuracan®	4462556	4039239000007933Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleuracan® B	4462505							N/A
Pleuracan® Back-Check Valve	4462564	403923900000281736	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600	5523682							N/A
Discifix® C	16700C							40392390000075933
Discifix® C	16500C	N/A						
Discifix® C	16495C	N/A						
Discifix® C	16560CSF	N/A						
Discifix® C	16901C	N/A						
Discifix® C	16615C	N/A						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000008082P	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	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							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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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							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	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasofix® Braunüle®	4268113B		NB0123					N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	4039239000007893C	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	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							N/A
Extension Line	4054393							N/A
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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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
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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Spiral Line	4091736		NB0123					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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	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	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4060407		NB0123					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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV 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							4039239000007973B
Drainobag® Lock 600 V	5523648	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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV 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
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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000014832Q	G2S 012974 0457 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	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							
Intrafix® Primeline	4062877		G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4062878		NB0123					N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063000A	40392390000007822W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000086533	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	4039239000008693B	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					
Infusomat® Space Line	8270074SP	40392390000086635	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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					

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	4039239000008632X	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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700410	40392390000008642Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4182190SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4180639SP							N/A
ProSet Infusomat® Space Line	4180020SP							N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	4039239000008712W	G1 012974 0607	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Original Perfusor® Line	4085129		NB0123					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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000014792Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	403923900000039ZP	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
														N/A
Infuvalve®	4094000N	40392390000008102A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	4039239000008112C	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495101R		NB0123					N/A
Safeflow Extension Set	4097154N	4039239000008152L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Safeflow Extension Set	4097145N		NB0123					N/A
Safeflow Extension Set	4097154		N/A					
Safeflow	409110H	4039239000008162N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	40392390000027222S	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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 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 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000077735	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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							403923900000207022
Sterican® Safety Needle	4670002S-01	40392390000076936	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000076834	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670053S-01							N/A
Sterican® Safety Needle	4670055S-01							N/A
Sterican® Safety Needle	4670055SBR							N/A
Sterican®	4650018	40392390000076834	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican®	4650034							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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022C	40392390000007752Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000076936	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	4039239000008522S	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898325		NB0123					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	4039239000008532U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898211		NB0123					N/A
Contiplex® D	4898235							N/A
Contiplex® C	4898115	40392390000085000	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	4039239000008552Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Ultraplex® 360	4892603CN							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	4039239000008502N	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® D	4892105-23							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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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						

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728615C		NB0123					N/A
Original Perfusor® Syringe 20 ml	8728623							N/A
Original Perfusor® Syringe 20 ml	8728623C	40392390000029923R	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728810F-04							N/A
Original Perfusor® Syringe 50 ml								N/A

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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	40392390000077939	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728844F-06							8728844F
Original Perfusor® Syringe 50 ml	8728844F-20							N/A
Original Perfusor® Syringe 50 ml	8728852F-04	40392390000029923R	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728852F-06							N/A
Original Perfusor® Syringe 50 ml	8728852F-20							N/A
Original Perfusor® Syringe 50 ml	8728861F-04	403923900000207124	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728861F-06							N/A
Original Perfusor® Syringe 50 ml	8728861F-20							N/A
Original Perfusor® Syringe 50 ml	8728845F-01	4039239000007802S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450100	4039239000009993R	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450120							N/A
Cystofix®	4450130							N/A

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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					N/A
Cystofix SG	4450414		B.BRAUN MEDICAL SAS					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					N/A
Cystofix	4450014		B.BRAUN MEDICAL SAS		TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)		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	4039239000000927Y	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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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

³ 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)

Schedule of Devices

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

Identification of the device(s) ³ (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 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 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

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

³ 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: BBMAG_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

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