

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-Str. 1, 34212 Melsungen, Germany Contact Person: Dr. Henning Schlicht, Head of Regulatory Affairs, Email: henning.schlicht@bbraun.com
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 type="checkbox"/> See attached schedule
Notified body number (if applicable)	0123	<input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	G7 012974 0600 G1 012974 0608	<input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26	<input type="checkbox"/> See attached schedule
End date of extended validity/transition period	2027-12-31	<input 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:

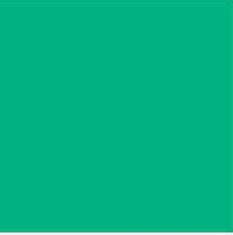
- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

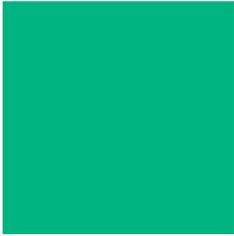
➤ **Device(s) as listed in the attached schedule**

- 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	Berlin, 2024-02-08	Berlin, 2024-02-08
Signature	See electronic signature	See electronic signature
Print Name	Dr. Susanne Vogelbein	Dr. Henning Schlicht
Title	Head of QM	Head of RA
Contact Details (at least email)	susanne.vogelbein@bbraun.com	henning.schlicht@bbraun.com
Version of document	V01	



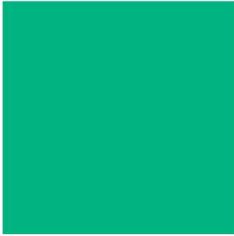


Schedule of Devices

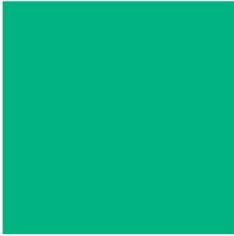
The above Manufacturer's Declaration is valid for the following devices:

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)
14115020	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14115040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14120040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14125040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14130040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14135040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14140040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14150040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14115080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14120080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14025080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
14130080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor

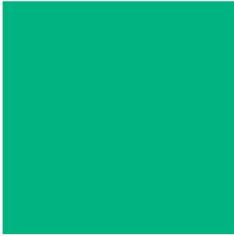
³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



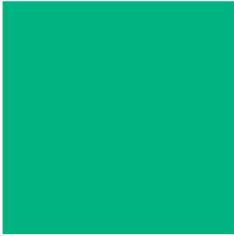
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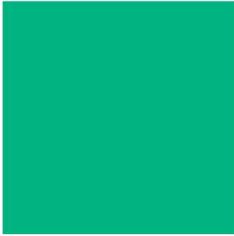
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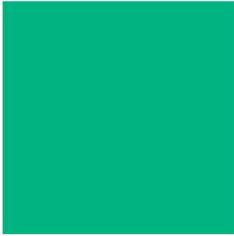
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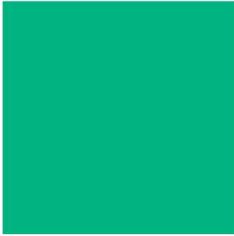
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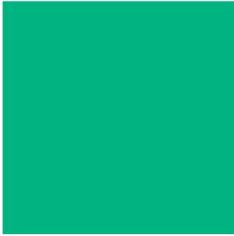
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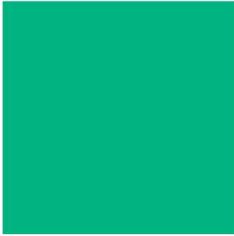
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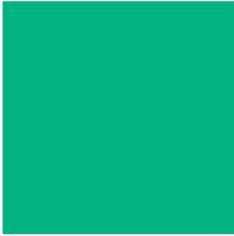
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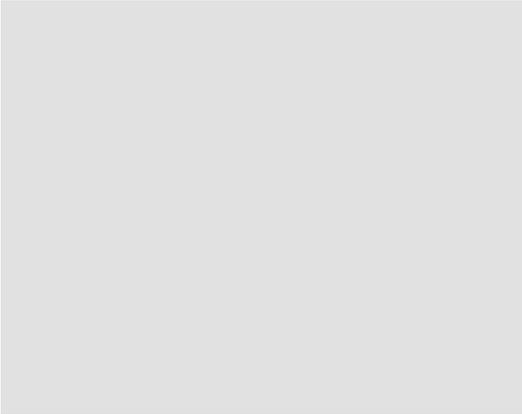
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35330020	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35340020	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35350020	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35360020	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35370020	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35380020	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35330040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35340040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35340040
35350040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35350040
35360040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35360040
35370040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35380040	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35330060	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35340060	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35340060
35350060	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35350060
35360060	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35360060



35370060	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35380060	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35330080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35340080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35340080
35350080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35350080
35360080	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35360080
35330100	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35340100	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35350100	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35360100	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35330120	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35340120	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35340120
35350120	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35350120
35360120	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35360120
35330150	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	no successor
35340150	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35340150
35350150	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35350150
35360150	G7 012974 0600	2024-05-26	TÜV Süd CE0123	TÜV Süd CE0123	2027-12-31	35360150

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