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

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule

[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.

Effective

Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ 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 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:

[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

- ☐ 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.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- **X** 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.

X A notified body has issued the attached certificate for the MDR-compliant QMS.

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

Effective

- 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:

B. Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen

Melsungen; 2024-03-21

See below electronic signature	See below electronic signature
Dr. Frank Ritz	**Dr. Joachim Bünger**
VP QM Pharma & PRRC	*Director Template and Submission Management & PRRC*
Email: frank.ritz@bbraun.com	Email: joachim.buenger@bbraun.com

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)
Glycine 1.5% B. Braun FR29914 FREU914 FREU934 FREU954 FREU974	G1 012974 0607 Rev. 02	26.05.2024	TÜV SÜD Product Service GmbH No. 0123	TÜV SÜD Product Service GmbH No. 0123	31.12.2028	NA
Aqua B. Braun 387872 387873 387874 442464 442465 442466 3521380 3521390 3553949 3553957 3637007 3637011	G1 012974 0607 Rev. 02	26.05.2024	TÜV SÜD Product Service GmbH No. 0123	TÜV SÜD Product Service GmbH No. 0123	31.12.2028	NA

[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

0065729E 0066571E 0069415E 0082423E 0082479E FREU812 FREU852 FREU912 FREU932						
NaCl 0.9 % B. Braun 3521360 3521370 3570100 3570110 3570120 3570130 3570140 3570150 3570160 3570170 3637006 0066569E 0066570E 0069414E 3570460 3570470 3570480 391858 391859 391860 3570300 3570301 3570310 3570330 3570340 3570350	G1 012974 0607 Rev. 02	26.05.2024	TÜV SÜD Product Service GmbH No. 0123	TÜV SÜD Product Service GmbH No. 0123	31.12.2028	NA

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3570360 3570370 3570380 3570390 3570410 3570420 3637010 FREU850 FREU910 FREU950 FREU930 FREU970 450268 450272						
Ringer B. Braun 3570000 3570010 3570020 3570030 3570040 3570050 3570060 FREU864 FREU924 FREU944 FREU964 FREU984	G1 012974 0607 Rev. 02	26.05.2024	TÜV SÜD Product Service GmbH No. 0123	TÜV SÜD Product Service GmbH No. 0123	31.12.2028	NA
Ringer Lactate B. Braun 3570490 Ecolav 30ML 3570500 Ecolav 100ML 3570510 Ecolav 500ML 3570520 Ecolav 500ML 3570530 ESTERICLEAN 500ML	G1 012974 0607 Rev. 02	26.05.2024	TÜV SÜD Product Service GmbH No. 0123	TÜV SÜD Product Service GmbH No. 0123	31.12.2028	**Ringer B. Braun** 3570611 Ecolav 30ML 3570610 Ecolav 100ML 3570614 Ecolav 500ML 3570612 Ecolav 500ML 3570613 ESTERICLEAN 500ML

Effective

Title: MDR_Manufacturer Declaration_Class IIb Irrigation Solution Initiator: Alain ? Bordon

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

UserName: Labeirie, Eva (labeevch)
Title: HC-RA-CH01-Global-Regulatory-Affairs-Manager
Date: Thursday, 21 March 2024, 16:29 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Friday, 22 March 2024, 07:45 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Thursday, 28 March 2024, 08:48 W. Europe Daylight Time
Meaning: Approve Document
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