



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 Medical
Manufacturer address and contact details	26, rue Armengaud – 92210 Saint-Cloud – France Manuelle SCHNEIDER PONSOT
Single Registration Number (SRN) (if available)	FR-MF-000000674

Authorised Representative name (if applicable)	NA
Authorised Representative address and contact details	NA
Single Registration Number (SRN) (if available)	NA

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)	GMED	<input type="checkbox"/> See attached schedule
Notified body number (if applicable)	0459	<input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	Click or tap to enter text.	<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)	Click or tap to enter text.	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	Click or tap to enter text.	<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:

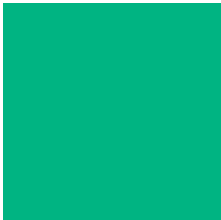
➤ **Directive Certificate(s)** as listed above or in the attached schedule

- 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 Medical	B. Braun Medical
Location & Date	In Chasseneuil-du-Poitou, January 12th, 2024	In Saint-Cloud, January 12th, 2024
Signature	See electronic signature	See electronic signature
Print Name	Catherine BOISMENU	Manuelle SCHNEIDER PONSOT
Title	Deputy Director in charge of Quality and delegated Regulatory Affairs	Director of Regulatory and Pharmaceutics Operations General Manager

DocuSigned by:

Catherine Boismenu

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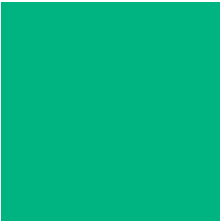
DocuSigned by:

Manuelle Schneider

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Contact Details (at least email)	Gra_chasseneuil@bbraun.com	Manuelle.schneider_ponsot@bbraun.com
Version of document	1	

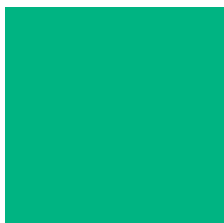


Schedule of Devices

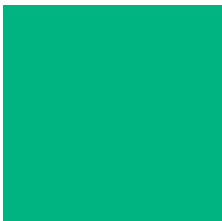
The above Manufacturer’s Declaration is valid for the following devices:

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)
Surecan® Safety II – see hereafter the list of references	10488 rev.14	26/05/2024	GMED 0459	GMED 0459	31/12/2027	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)



References	DESIGNATION	Directive 93/42/CEE	EC Certificate
4447042	SURECAN SAFETY II 19Gx12mm	Annex II.3	n° 10488
4447000	SURECAN SAFETY II 19Gx15mm	Annex II.3	n° 10488
4447001	SURECAN SAFETY II 19Gx20mm	Annex II.3	n° 10488
4447002	SURECAN SAFETY II 19Gx25mm	Annex II.3	n° 10488
4447003	SURECAN SAFETY II 19Gx32mm	Annex II.3	n° 10488
4447004	SURECAN SAFETY II 19Gx38mm	Annex II.3	n° 10488
4447043	SURECAN SAFETY II 20Gx12mm	Annex II.3	n° 10488
4447005	SURECAN SAFETY II 20Gx15mm	Annex II.3	n° 10488
4447006	SURECAN SAFETY II 20Gx20mm	Annex II.3	n° 10488
4447007	SURECAN SAFETY II 20Gx25mm	Annex II.3	n° 10488
4447008	SURECAN SAFETY II 20Gx32mm	Annex II.3	n° 10488
4447009	SURECAN SAFETY II 20Gx38mm	Annex II.3	n° 10488
4447044	SURECAN SAFETY II 22Gx12mm	Annex II.3	n° 10488
4447010	SURECAN SAFETY II 22Gx15mm	Annex II.3	n° 10488
4447011	SURECAN SAFETY II 22Gx20mm	Annex II.3	n° 10488
4447012	SURECAN SAFETY II 22Gx25mm	Annex II.3	n° 10488
4447013	SURECAN SAFETY II 22Gx32mm	Annex II.3	n° 10488
4447057	SURECAN SAFETY II CARESITE Y 19Gx12mm	Annex II.3	n° 10488
4447045	SURECAN SAFETY II CARESITE Y 19Gx15mm	Annex II.3	n° 10488
4447046	SURECAN SAFETY II CARESITE Y 19Gx20mm	Annex II.3	n° 10488
4447047	SURECAN SAFETY II CARESITE Y 19Gx25mm	Annex II.3	n° 10488
4447048	SURECAN SAFETY II CARESITE Y 19Gx32mm	Annex II.3	n° 10488
4447049	SURECAN SAFETY II CARESITE Y 19Gx38mm	Annex II.3	n° 10488
4447058	SURECAN SAFETY II CARESITE Y 20Gx12mm	Annex II.3	n° 10488
4447050	SURECAN SAFETY II CARESITE Y 20Gx15mm	Annex II.3	n° 10488
4447051	SURECAN SAFETY II CARESITE Y 20Gx20mm	Annex II.3	n° 10488
4447052	SURECAN SAFETY II CARESITE Y 20Gx25mm	Annex II.3	n° 10488
4447053	SURECAN SAFETY II CARESITE Y 20Gx32mm	Annex II.3	n° 10488



4447059	SURECAN SAFETY II CARESITE Y 22Gx12mm	Annex II.3	n° 10488
4447054	SURECAN SAFETY II CARESITE Y 22Gx15mm	Annex II.3	n° 10488
4447055	SURECAN SAFETY II CARESITE Y 22Gx20mm	Annex II.3	n° 10488
4447056	SURECAN SAFETY II CARESITE Y 22Gx25mm	Annex II.3	n° 10488

Certificat de réalisation

Identifiant d'enveloppe: 05E915B2F66D42C084A9C0F7BEBDDC93

État: Complétée

Objet: Complétez l'enveloppe avec DocuSign : EC Declaration of Conformity_ Surecan Safety II.pdf, SSII...

Enveloppe source:

Nombre de pages du document: 11

Signatures: 8

Émetteur de l'enveloppe:

Nombre de pages du certificat: 5

Paraphe: 0

Christine GABORIAUD

Signature dirigée: Activé

Carl-Braun-Str. 1

Horodatage de l'enveloppe: Activé

Melsungen, Hesse 34212

Fuseau horaire: (UTC+01:00) Amsterdam, Berlin, Berne, Rome, Stockholm, Vienne

christine.gaboriaud@bbraun.com

Adresse IP: 90.83.170.129

Suivi du dossier

État: Original

Titulaire: Christine GABORIAUD

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christine.gaboriaud@bbraun.com

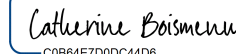
Événements de signataire**Signature****Horodatage**

Catherine Boismenu

catherine.boismenu@bbraun.com

Deputy Director in charge of Quality and delegated
Regulatory AffairsNiveau de sécurité: E-mail, Authentification de
compte (aucune)

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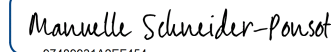
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Signature complétée	Sécurité vérifiée	19/01/2024 10:07:40
Complétée	Sécurité vérifiée	19/01/2024 10:07:40

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