



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:

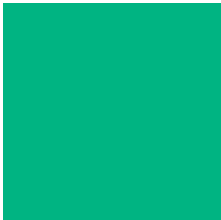
➤ **Directive Certificate(s)** as listed above or in the attached schedule

- 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:

Page 4 of 7
Catherine Boismenu

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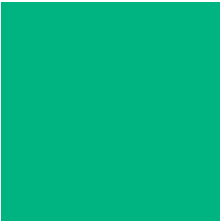
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Contact Details (at least email)	Gra_chasseneuil@bbraun.com	Manuelle.schneider_ponsot@bbraun.com
Version of document	1	

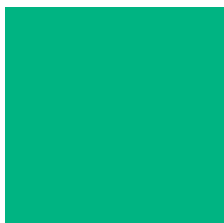


Schedule of Devices

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)
Winged Surecan® – 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/EEc	EC Certificate
4448286	WINGED SURECAN 19Gx15mm	Annexe II.3	n° 10488
4448294	WINGED SURECAN 19Gx20mm	Annexe II.3	n° 10488
4448308	WINGED SURECAN 19Gx25mm	Annexe II.3	n° 10488
4448332	WINGED SURECAN 20Gx15mm	Annexe II.3	n° 10488
4448340	WINGED SURECAN 20Gx20mm	Annexe II.3	n° 10488
4448359	WINGED SURECAN 20Gx25mm	Annexe II.3	n° 10488
4448367	WINGED SURECAN 20Gx30mm	Annexe II.3	n° 10488
4448375	WINGED SURECAN 22Gx12mm	Annexe II.3	n° 10488
4448383	WINGED SURECAN 22Gx15mm	Annexe II.3	n° 10488
4448391	WINGED SURECAN 22Gx20mm	Annexe II.3	n° 10488
4448405	WINGED SURECAN 22Gx25mm	Annexe II.3	n° 10488
4448430	WINGED SURECAN Y-SITE 19Gx20mm	Annexe II.3	n° 10488
4448448	WINGED SURECAN Y-SITE 19Gx25mm	Annexe II.3	n° 10488
4448472	WINGED SURECAN Y-SITE 20Gx15mm	Annexe II.3	n° 10488
4448480	WINGED SURECAN Y-SITE 20Gx20mm	Annexe II.3	n° 10488
4448499	WINGED SURECAN Y-SITE 20Gx25mm	Annexe II.3	n° 10488
4448529	WINGED SURECAN Y-SITE 22Gx15mm	Annexe II.3	n° 10488
4448537	WINGED SURECAN Y-SITE 22Gx20mm	Annexe II.3	n° 10488
4448545	WINGED SURECAN Y-SITE 22Gx25mm	Annexe II.3	n° 10488
4448553	WINGED SURECAN Y-SITE 22Gx30mm	Annexe II.3	n° 10488

Certificat de réalisation

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État: Complétée

Objet: Complétez l'enveloppe avec DocuSign : EC Declaration of Conformity_Winged Surecan.pdf, Winged S...

Enveloppe source:

Nombre de pages du document: 10

Signatures: 8

Émetteur de l'enveloppe:

Nombre de pages du certificat: 5

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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

Emplacement: DocuSign

17/01/2024 14:03:48

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)DocuSigned by:

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En utilisant l'adresse IP: 90.83.170.129

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Consultée: 17/01/2024 16:50:03

Signée: 17/01/2024 16:51:06

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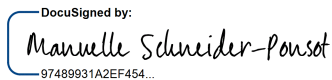
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Manuelle Schneider-Ponsot

manuelle.schneider_ponsot@bbraun.com

Directeur des Oparations Reglementaires et
Pharmaceutiques

B. Braun Medical

Niveau de sécurité: E-mail, Authentification de
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