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SHARING EXPERTISE

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 Emmanuel DA SILVA
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	☐ See attached schedule
Notified body number (if applicable)	0459	☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	Click or tap to enter text.	☒ 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.	☒ See attached schedule
End date of extended validity/transition period	Click or tap to enter text.	☒ 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 Saint-Cloud, December 04th, 2024**	**In Chasseneuil-du-Poitou, December 04th, 2024**
Signature	**See electronic signature**	**See electronic signature**
Print Name	**Emmanuel DA SILVA** Signé par : Emmanuel DA SILVA E61FF06A8A98445...	**Catherine BOISMENU** DocuSigned by: Catherine Boismenu C0B64E7D0DC44D6...
Title	**PRRC** **Quality Management System Manager**	**Deputy Director in charge of Quality and delegated Regulatory Affairs**

Contact Details (at least email)	**emmanuel.da_silva@bbraun.com**	**gra_chasseneuil@bbraun.com**
Version of document	**3**	

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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)
Celsite® Venous Access Ports – see hereafter the list of references	8894 rev.20 9637 rev.25	12/05/2024 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)

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REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
04430143*	Celsite® ST215	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430026*	Celsite® T201	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430395*	Celsite® ST201	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04432045*	Celsite® ST201C	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430034*	Celsite® T201F	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430409*	Celsite® ST201F	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433149*	Celsite® ST201H	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430417*	Celsite® ST201P	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430085*	Celsite® T205	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430893*	Celsite® ST205	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433742*	Celsite® Babyport®	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433734*	Celsite® Brachial	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430018*	Celsite® T301	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430425*	Celsite® ST301	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04432096*	Celsite® ST301C	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430000*	Celsite® T301F	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430433*	Celsite® ST301F	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04432452*	Celsite® T301H	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04432460*	Celsite® ST301H	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430387*	Celsite® T301P	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430441*	Celsite® ST301P	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433726*	Celsite® ST301OTW	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436903*	Celsite® T305	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433750*	Celsite® ST305	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436962*	Celsite® ST305C	Annex II.3 - Annex II.4	n° 9637 - n° 8894

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REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
04433556*	Celsite® ST305H	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436920*	Celsite® ST305L	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436946*	Celsite® ST305P	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436709*	Celsite® ST311	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436717*	Celsite® ST311F	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436725*	Celsite® ST315	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436814*	Celsite® ST311H	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430140*	Celsite® ST201ECG	Annex II.3 – Annex II.4	n° 9637 - n° 8894
04440140*	Celsite® ST201F ECG	Annex II.3 – Annex II.4	n° 9637 - n° 8894
04430111*	Celsite® ST205ECG	Annex II.3 – Annex II.4	n° 9637 - n° 8894
04440111*	Celsite® ST205F ECG	Annex II.3 – Annex II.4	n° 9637 - n° 8894
04433823*	Celsite® ST301G	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433807*	Celsite® ST201G	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433842*	Celsite® Babyport® S	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436710*	Celsite® ST315L	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436806*	Celsite® ST205H	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430895*	Celsite® ST205L	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430894*	Celsite® ST205P	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430440*	Celsite® BT301P	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04436945*	Celsite® BT305P	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430150*	Celsite® T201 ECG	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04440150*	Celsite® T201F ECG	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04430222*	Celsite® T205 ECG	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04440222*	Celsite® T205F ECG	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433850*	Celsite® SNT305F	Annex II.3 - Annex II.4	n° 9637 - n° 8894

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REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
04433875*	Celsite® SNT215F	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433876*	Celsite® SNT201F	Annex II.3 - Annex II.4	n° 9637 - n° 8894
04433851*	Celsite® SNT301F	Annex II.3 - Annex II.4	n° 9637 - n° 8894

* Reference intended for high pressure injection of contrast media

Certificat de réalisation

Identifiant d'enveloppe: 321DA8D6-8C70-4CDC-9AD8-F816290ED413

État: Complétée

Objet: Complétez avec Docusign : Celsite Venous access ports_Manufacturer's declaration_v3.pdf, Celsit...

Enveloppe source:

Nombre de pages du document: 40

Signatures: 10

Émetteur de l'enveloppe:

Nombre de pages du certificat: 5

Paraphe: 0

Christine GABORIAUD

Carl-Braun-Str. 1

Signature dirigée: Activé

Melsungen, Hesse 34212

Horodatage de l'enveloppe: Activé

christine.gaboriaud@bbraun.com

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

Adresse IP: 77.135.193.210

Suivi du dossier

État: Original
04/12/2024 12:04:56

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christine.gaboriaud@bbraun.com

Emplacement: DocuSign

Événements de signataire	Signature	Horodatage
Emmanuel DA SILVA emmanuel.da_silva@bbraun.com Responsable SMQ Saint-Cloud Niveau de sécurité: E-mail, Authentification de compte (aucune)	Signé par : Emmanuel DA SILVA E61FF06A8A98445... Sélection d'une signature : Style présélectionné En utilisant l'adresse IP: 194.206.59.59	Envoyée: 04/12/2024 12:10:58 Consultée: 04/12/2024 15:54:41 Signée: 04/12/2024 15:55:28

Divulgation relative aux Signatures et aux Dossiers électroniques:
Accepté: 04/12/2024 15:54:41
ID: 2447466a-a13c-4293-89cb-b5569ecfe8e3

Catherine Boismenu catherine.boismenu@bbraun.com Deputy Director in charge of Quality and delegated Regulatory Affairs Niveau de sécurité: E-mail, Authentification de compte (aucune)	DocuSigned by: Catherine Boismenu C0B64E7D0DC44D6... Sélection d'une signature : Style présélectionné En utilisant l'adresse IP: 77.135.193.210	Envoyée: 04/12/2024 15:55:35 Consultée: 04/12/2024 17:32:20 Signée: 04/12/2024 17:33:07

Divulgation relative aux Signatures et aux Dossiers électroniques:
Accepté: 15/02/2022 15:28:10
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Événements de livraison à l'éditeur	État	Horodatage

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Enveloppe envoyée	Haché/crypté	04/12/2024 12:10:58
Livraison certifiée	Sécurité vérifiée	04/12/2024 17:32:20
Signature complétée	Sécurité vérifiée	04/12/2024 17:33:07
Complétée	Sécurité vérifiée	04/12/2024 17:33:19

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