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

[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	☒ See attached schedule
Notified body number (if applicable)	0123	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	(1) G1 012974 0607 Rev.02; (2) G7 012974 0612 Rev.00; (3) G7 012974 0593 Rev.01; (4) G7 012974 0592 Rev.02;	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	(1) 2024-05-26; (2) 2024-05-26; (3) 2024-05-26; (4) 2024-05-26	☒ See attached schedule
End date of extended validity/transition period	2027-12-31	☒ 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:

[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

☐ 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:

☐ 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	**Melsungen, 2024-07-25**	**Melsungen, 2024-07-25**
Signature	**See electronic signature**	**See electronic signature**
Print Name	**(1) Thomas Brand; (2) Dr. Frank Ritz**	**(3) Dr. Stefan Seidel; (4) Dr. Joachim Buenger**
Title	**(1) Vice President Quality Management for non-active Medical Devices; (2) Vice**	**(3) Head of Regulatory Affairs CoE Infusion & Pain Therapy;**

	President QM Pharma; Hospital Care Division	**(4) Director Template & Submission Mgmt**
Contact Details (at least email)	**BBMAG_HC@bbraun.com**	**BBMAG_HC@bbraun.com**
Version of document	**Version 4.0**	

Effective

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)	Article name (MDR Application)
4513150	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Perifix® Catheter
4513258	G7 012974 0612 Rev.00; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Perifix® Catheter
4513177							Perifix® Catheter
4515048							Perifix® SoftTip Catheter
4513258N-01							Perifix® Catheter NRFit®
4513150N-01							Perifix® Catheter NRFit®
4513177N-01							Perifix® Catheter NRFit®

[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)

Schedule of Devices

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4515048N-01							Perifix® SoftTip Catheter NRFit®
4513150C							Perifix® ONE Catheter
4513258C							Perifix® ONE Catheter
45132581N-01							Perifix® ONE Catheter NRFit®
45131501N-01							Perifix® ONE Catheter NRFit®

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Schedule of Devices

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4514009	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Perifix 400
4514017	G7 012974 0612 Rev.00; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Perifix 401
4514025							Perifix 402
4514513							Perifix 451
4510097							Perifix Soft Tip 701
4510216							Perifix Soft Tip 700
4517309							Perifix Soft Tip 730
4517504							Perifix Soft Tip 750
4511000							Perifix 100
4513002							Perifix 300
4513010							Perifix 301

Effective

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Schedule of Devices

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4513029							Perifix 302
4513100							Perifix 310
4514009N-01							Perifix 400 NRFit
4514017N-01							Perifix 401 NRFit
4514025N-01							Perifix 402 NRFit
4510097N-01							Perifix Soft Tip 701 NRFit
4517309N-01							Perifix Soft Tip 730 NRFit
4513002N-01							Perifix 300 NRFit
4514009C							Perifix ONE 400
4514017C							Perifix ONE 401

Effective

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Schedule of Devices

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4514025C							Perifix ONE 402
4514183C							Perifix ONE 418
4514513C							Perifix ONE 451
45140171N-01							Perifix ONE 401 NRFit
45140251N-01							Perifix ONE 402 NRFit
4514203							Perifix 420
4514211							Perifix 421
4514300							Perifix 430
4514319							Perifix 431
4516206							Perifix 620
4510291							Perifix Soft Tip 900
4510305							Perifix Soft Tip 901
4514211N-01							Perifix 421 NRFit

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Schedule of Devices

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4510305N-01							Perifix Soft Tip 901 NRFit
4514203C							Perifix ONE 420
4514211C							Perifix ONE 421
4514319C							Perifix ONE 431
4512006C							Perifix ONE Paed Set 18
4512014C							Perifix ONE Paed Set 20
45142111N-01							Perifix ONE 421 NRFit
45120061N-01							Perifix ONE Paed Set 18 NRFit
45120141N-01							Perifix ONE Paed Set 20 NRFit

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Schedule of Devices

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4556674	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Espocan
4556666	G7 012974 0612 Rev.00; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Espocan
4556747							Espocan with Docking System
4556763							Espocan with Docking System
4556674N-01							Espocan NRFit
4556666N-01							Espocan NRFit

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Schedule of Devices

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4556747N-01							Espocan NRFit with Docking System
4556763N-01							Espocan NRFit with Docking System
4160177	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Certofix® Mono Paed S 110
4160177-01	G7 012974 0593 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Certofix® Mono Paed S 110
4160177-04							Certofix® Mono Paed S 110
4160185							Certofix® Mono S 215

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Schedule of Devices

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4160185-07							Certofix® Mono S 215
4160185E							Certofix® Mono 215
4160185E-07							Certofix® Mono 215
4160207							Certofix® Mono S 220
4160207-07							Certofix® Mono S 220
4160207E							Certofix® Mono 220
4160207E-07							Certofix® Mono 220
4160207R							Certofix® Mono 220 R
4160215							Certofix® Mono V 220
4160215-07							Certofix® Mono V 220

Effective

[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)

Schedule of Devices

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4160223							Certofix® Mono S 315
4160223-07							Certofix® Mono S 315
4160223E							Certofix® Mono 315
4160223E-07							Certofix® Mono 315
4160231							Certofix® Mono V 315
4160231-07							Certofix® Mono V 315
4160258							Certofix® Mono S 320
4160258-07							Certofix® Mono S 320
4160258E							Certofix® Mono 320
4160258E-07							Certofix® Mono 320

Effective

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Schedule of Devices

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4160258R							Certofix® Mono 320 R
4160258S							Certofix® Safety Mono S 320
4160258S-07							Certofix® Safety Mono S 320
4160266							Certofix® Mono V 320
4160266-07							Certofix® Mono V 320
4160282							Certofix® Mono S 330"
4160282-07							Certofix® Mono S 330
4160282E							Certofix® Mono 330
4160282E-07							Certofix® Mono 330"

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Schedule of Devices

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4160282S							Certofix® Safety Mono S 330
4160282S-07							Certofix® Safety Mono S 330
4160290							Certofix® Mono V 330
4160290-07							Certofix® Mono V 330
4160304							Certofix® Mono S 420"
4160304-07							Certofix® Mono S 420"
4160304E							Certofix® Mono 420
4160304E-07							Certofix® Mono 420

Effective

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Schedule of Devices

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4160304R							Certofix® Mono 420 R
4160320							Certofix® Mono V 420
4160320-07							Certofix® Mono V 420
4160509							Certofix® Mono S 415
4160509-07							Certofix® Mono S 415
4160509E							Certofix® Mono 415
4160509E-07							Certofix® Mono 415
4160517							Certofix® Mono V 415
4160517-07							Certofix® Mono V 415
4160578							Certofix® Trio HF S 1215

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Schedule of Devices

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4160578-07							Certofix® Trio HF S 1215
4160586							Certofix® Trio HF S 1220
4160586-07							Certofix® Trio HF S 1220
4160614							Certofix® Trio HF V 1215
4160614-07							Certofix® Trio HF V 1215
4160622							Certofix® Trio HF V 1220
4160622-07							Certofix® Trio HF V 1220

Effective

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Schedule of Devices

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4160762							Certofix® Mono S 430
4160762-07							Certofix® Mono S 430
4160762E							Certofix® Mono 430
4160762E-07							Certofix® Mono 430
4160789							Certofix® Mono V 430
4160789-07							Certofix® Mono V 430
4161157E							Certofix® Trio 715
4161157E-07							Certofix® Trio 715
4161159							Certofix® Trio S 715
4161159-07							Certofix® Trio S 715

Effective

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4161211							Certofix® Duo V 720
4161211-07							Certofix® Duo V 720
4161319							Certofix® Duo V 730
4161319-07							Certofix® Duo V 730
4162153							Certofix® Trio V 715
4162153-07							Certofix® Trio V 715
4162200E							Certofix® Duo 720
4162200E-07							Certofix® Duo 720
4162307E							Certofix® Duo 730
4162307E-07							Certofix® Duo 730

Effective

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4163206E							Certofix® Trio 720
4163206E-07							Certofix® Trio 720
4163214							Certofix® Trio V 720
4163214-07							Certofix® Trio V 720
4163303E							Certofix® Trio 730
4163303E-07							Certofix® Trio 730
4163306							Certofix® Trio S 730
4163306-07							Certofix® Trio S 730
4163306S							Certofix® Safety Trio S 730

[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)

Schedule of Devices

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4163306S-07							Certofix® Safety Trio S 730
4163311							Certofix® Trio V 730
4163311-07							Certofix® Trio V 730
4164156E							Certofix® Duo 715
4164156E-07							Certofix® Duo 715
4164158							Certofix® Duo S 715
4164158-07							Certofix® Duo S 715
4166159							Certofix® Duo V 715
4166159-07							Certofix® Duo V 715

[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)

Schedule of Devices

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4166841							Certofix® Quinto V 1215
4166841-07							Certofix® Quinto V 1215
4166852							Certofix® Quinto S 1220
4166852-07							Certofix® Quinto S 1220
4166852S							Certofix® Safety Quinto S 1220
4166852S-07							Certofix® Safety Quinto S 1220

Effective

[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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4166868							Certofix® Quinto V 1220
4166868-07							Certofix® Quinto V 1220
4166906							Certofix® Duo Paed S 408
4166906-07							Certofix® Duo Paed S 408
4166922							Certofix® Duo Paed S 413
4166922-07							Certofix® Duo Paed S 413
4166949							Certofix® Duo Paed S 420

Effective

[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)

Schedule of Devices

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4166949-07							Certofix® Duo Paed S 420
4167112							Certofix® Duo Paed S 508
4167112-07							Certofix® Duo Paed S 508
4167139							Certofix® Duo Paed S 513
4167139-07							Certofix® Duo Paed S 513
4167155							Certofix® Duo Paed S 520
4167155-07							Certofix® Duo Paed S 520

Effective

[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)

Schedule of Devices

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4167228							Certofix® Trio Paed S 508
4167228-07							Certofix® Trio Paed S 508
4167244							Certofix® Trio Paed S 513
4167244-07							Certofix® Trio Paed S 513
4167260							Certofix® Trio Paed S 520
4167260-07							Certofix® Trio Paed S 520
4167385							Certofix® Duo S 720

Effective

[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)

Schedule of Devices

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4167385-07							Certofix® Duo S 720
4167385S							Certofix® Safety Duo S 720
4167385S-07							Certofix® Safety Duo S 720
4167394							Certofix® Duo S 730
4167394-07							Certofix® Duo S 730
4167394S							Certofix® Safety Duo S 730
4167394S-07							Certofix® Safety Duo S 730
4167408							Certofix® Trio S 720

Effective

[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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4167408-07							Certofix® Trio S 720
4167408S							Certofix® Safety Trio S 720
4167408S-07							Certofix® Safety Trio S 720
4167511							Certofix® Duo HF V 920
4167511-07							Certofix® Duo HF V 920
4167538							Certofix® Duo HF V 1215
4167538-07							Certofix® Duo HF V 1215

Effective

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4167546							Certofix® Duo HF V 1220
4167546-07							Certofix® Duo HF V 1220
4167767							Certofix® Quattro V 815
4167767-07							Certofix® Quattro V 815
4167775							Certofix® Quattro V 820
4167775-07							Certofix® Quattro V 820

[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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4167775S							Certofix® Safety Quattro V 820
4167775S-07							Certofix® Safety Quattro V 820
4167783							Certofix® Quattro V 830
4167783-07							Certofix® Quattro V 830
4168518							Certofix® Duo HF V 715
4168518-07							Certofix® Duo HF V 715

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4168528							Certofix® Duo HF S 720
4168528-07							Certofix® Duo HF S 720
4168534							Certofix® Duo HF V 720
4168534-07							Certofix® Duo HF V 720
4160266P	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Certofix® protect Mono V 320
4160266P-07	G7 012974 0593 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Certofix® protect Mono V 320

[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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4160290P							Certofix® protect Mono V 330
4160290P-07							Certofix® protect Mono V 330
4160320P							Certofix® protect Mono V 420
4160320P-07							Certofix® protect Mono V 420
4160622P							Certofix® protect Trio HF V 1220
4160622P-07							Certofix® protect Trio HF V 1220
4160789P							Certofix® protect Mono V 430

[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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4160789P-07							Certofix® protect Mono V 430
4161211P							Certofix® protect Duo V 720
4161211P-07							Certofix® protect Duo V 720
4161319P							Certofix® protect Duo V 730
4161319P-07							Certofix® protect Duo V 730
4162153P							Certofix® protect Trio V 715
4162153P-07							Certofix® protect Trio V 715

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4163214P							Certofix® protect Trio V 720
4163214P-07							Certofix® protect Trio V 720
4163311P							Certofix® protect Trio V 730
4163311P-07							Certofix® protect Trio V 730
4166159P							Certofix® protect Duo V 715
4166159P-07							Certofix® protect Duo V 715

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4166868P							Certofix® protect Quinto V 1220
4166868P-07							Certofix® protect Quinto V 1220
4167767P							Certofix® protect Quattro V 815
4167767P-07							Certofix® protect Quattro V 815
4167775P							Certofix® protect Quattro V 820

[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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4167775P-07							Certofix® protect Quattro V 820
4167783P							Certofix® protect Quattro V 830
4167783P-07							Certofix® protect Quattro V 830
4168534P							Certofix® protect Duo HF V 720
4168534P-07							Certofix® protect Duo HF V 720
4501373	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	4521801	Spinocan®

Effective

[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)

Schedule of Devices

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4501390	G7 012974 0592 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Spinocan®
4509757 4509900						4522001	Spinocan®
4507401						4522201	Spinocan®
4507754						4522202	Spinocan®
4507908						4522203	Spinocan®
4506090						4522204	Spinocan®
4505751						4522501	Spinocan®
4505905						4522502	Spinocan®
4505913						4522503	Spinocan®
4502906 4504917						4522601	Spinocan®
4503902						4522701	Spinocan®
4502140						4522702	Spinocan®
4501900						4522703	Spinocan®
4501918						4522901	Spinocan®

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4502035						4532201	Pencan
4502167						4532501	Pencan
4502159						4532502	Pencan
4502019						4532503	Pencan
4502043						4532504	Pencan
4502116						4532506	Pencan
4502175						4532701	Pencan
4502027						4532702	Pencan
4502051						4532703	Pencan
4502124						4532705	Pencan
4502132						4532706	Pencan
4504771						4542601	Atraucan®
4504763						4542602	Atraucan®
4504739						4542603	Atraucan®
4501390N-01 4501373N-01						4521801N	Spinocan®
4509757N-01 4509900N-01						4522001N	Spinocan®
4507401N-01						4522201N	Spinocan®

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4507754N-01						4522202N	Spinocan®
4507908N-01						4522203N	Spinocan®
4506090N-01 4506095N-01						4522204N	Spinocan®
4505751N-01						4522501N	Spinocan®
4505905N-01						4522502N	Spinocan®
4505913N-01						4522503N	Spinocan®
4502906N-01 4504917N-01						4522601N	Spinocan®
4503902N-01						4522701N	Spinocan®
4502140N-01						4522702N	Spinocan®
4501900N-01 4501901N-01 4501918N-01						4522901N	Spinocan®
4502035N-01						4532201N	Pencan
4502167N-01						4532501N	Pencan
4502159N-01						4532502N	Pencan
4502019N-01						4532503N	Pencan
4502043N-01 4502044N-01						4532504N	Pencan
4502116N-01						4532506N	Pencan

Effective

[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)

Schedule of Devices

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4502117N-01						4532506N	Pencan
4502120N-01						4532507N	Pencan
333877N-01						4532510N	Pencan
4502175N-01						4532701N	Pencan
4502027N-01						4532702N	Pencan
4502051N-01 4502052N-01						4532703N	Pencan
4502124N-01 4502125N-01						4532705N	Pencan
4502132N-01						4532706N	Pencan
4502035-13	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Pencan
4502167-13	G7 012974 0592 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Pencan
4502159-13							Pencan
4502019-01							Pencan
4502019-10							Pencan
4502043-13							Pencan
4502116-13							Pencan

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4502120-13							Pencan
4502175-13							Pencan
4502027-01							Pencan
4502027-10							Pencan
4502051-13							Pencan
4502124-13							Pencan
4502132-13							Pencan
4501373-13							Spinocan®
4501390-01							Spinocan®
4501390-10							Spinocan®
4501144						4501144-13	Spinocan®
4501195						4501195-13	Spinocan®
4509757-13						N/A	Spinocan®
4509900-01							Spinocan®
4509900-10							Spinocan®
4507401-13							Spinocan®
4507754-13							Spinocan®
4507908-01							Spinocan®

Effective

[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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4507908-10							Spinocan®
4506090-13							Spinocan®
4506014-03							Spinocan®
4505751-01							Spinocan®
4505751-10							Spinocan®
4505905-01							Spinocan®
4505905-10							Spinocan®
4505913-13							Spinocan®
4502906-01							Spinocan®
4502906-10							Spinocan®
4504917-13							Spinocan®
4503902-01							Spinocan®
4503902-10							Spinocan®
4502140-13							Spinocan®
4501900-13							Spinocan®
4501918-13							Spinocan®

Effective

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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)	Article name (MDR Application)
4512453	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Perican
4512200	G7 012974 0612 Rev.00; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Perican
4512383							Perican
4512588							Perican
4512782							Perican
4502078							Perican Paed
4502094							Perican Paed
4502302							Perican Paed
4512383N-01							Perican NRFit
4512200N-01							Perican NRFit
4512782N-01							Perican NRFit

[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)

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)	Article name (MDR Application)
4512453N-01							Perican NRFit
4512785N-01							Perican NRFit
4512784N-01							Perican NRFit
4502078N-01							Perican Paed NRFit
4502094N-01							Perican Paed NRFit
4502302N-01							Perican Paed NRFit
4502400	G1 012974 0607 Rev.02;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A	Epican Paed
4502418	G7 012974 0612 Rev.00; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31		Epican Paed
4502426							Epican Paed
4502400N-01							Epican Paed NRFit

[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)

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)	Article name (MDR Application)
4502418N-01							Epican Paed NRFit
4502426N-01							Epican Paed NRFit

Effective

[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)

Document History

Version	Description of Change
1.0	Initial version
2.0	Revision numbers of MDD certificates were added
3.0	Removed BUDI number, article name moved to the end of the table, article number changed for identification of device and substitute device.
4.0	Changed contact information e-mail address

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

UserName: Seidel, Stefan (seidstde)
Title: Vice President Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 31 July 2024, 17:13 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Seidel, Stefan (seidstde)
Title: Vice President Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 31 July 2024, 17:21 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Thursday, 01 August 2024, 07:03 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 01 August 2024, 10:02 W. Europe Daylight Time
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Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Tuesday, 06 August 2024, 07:57 W. Europe Daylight Time
Meaning: Approve Document
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Title: BBMAG_LM_confirmation letter_ Regulation EU 2023_607_G12 Initiator: Anja Mai

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

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Title: HC-QM-DE08 Vice President QM Applications Hospital Care
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