

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	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	0123	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	(1) G1 012974 0607; (2) G7 012974 0612; (3) G7 012974 0593; (4) G7 012974 0592;	<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)	(1) 2024-05-26; (2) 2024-05-26; (3) 2024-05-26; (4) 2024-05-26	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	2027-12-31	<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:

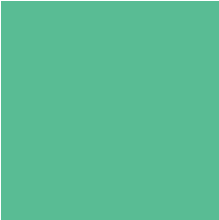
- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ 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 Melsungen AG	B. Braun Melsungen AG
Location & Date	Melsungen, 2024-04-15	Melsungen, 2024-04-15
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; (4) Director Template & Submission Mgmt



	President QM Pharma; Hospital Care Division	
Contact Details (at least email)	BBMAG-HC@bbraun.com	BBMAG-HC@bbraun.com
Version of document	Version 1.0	

B. Braun Melsungen AG - Document No.: G12 - Version: 1.0 - Document ID: RE-QM-DIV-000445 - Effective Date: 2024-05-06
Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G12

Schedule of Devices

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

Effective

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	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Perifix® Catheter	4513150	403923900000023832S					
Perifix® Catheter	4513258	G1 012974 0607; G7 012974 0612; NB0123					
Perifix® Catheter	4513177						
Perifix® Soft Tip Catheter	4515048						
Perifix® Catheter NRFit®	4513258N-01						
Perifix® Catheter NRFit®	4513150N-01						
Perifix® Catheter NRFit®	4513177N-01						
		G1 012974 0607; G7 012974 0612; NB0123	2024-05-26 2024-05-26	TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123)	2027-12-31 2027-12-31	N/A

Effect

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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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Perifix® SoftTip Catheter NRFit®	4515048N-01						
Perifix® ONE Catheter	4513150C						
Perifix® ONE Catheter	4513258C						
Perifix® ONE Catheter NRFit®	45132581N-01						
Perifix® ONE Catheter NRFit®	45131501N-01						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Perifix 400	4514009	40392390000023842U		G1 012974 0607;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A
Perifix 401	4514017			G7 012974 0612; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	
Perifix 402	4514025							
Perifix 451	4514513							
Perifix Soft Tip 701	4510097							
Perifix Soft Tip 700	4510216							
Perifix Soft Tip 730	4517309							
Perifix Soft Tip 750	4517504							
Perifix 100	4511000							
Perifix 300	4513002							
Perifix 301	4513010							Effect

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Perifix 302	4513029						
Perifix 310	4513100						
Perifix 400 NRFit	4514009N-01						
Perifix 401 NRFit	4514017N-01						
Perifix 402 NRFit	4514025N-01						
Perifix Soft Tip 701 NRFit	4510097N-01						
Perifix Soft Tip 730 NRFit	4517309N-01						
Perifix 300 NRFit	4513002N-01						
Perifix ONE 400	4514009C						
Perifix ONE 401	4514017C						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Perifix ONE 402	4514025C						
Perifix ONE 418	4514183C						
Perifix ONE 451	4514513C						
Perifix ONE 401 NRFit	45140171N- 01						
Perifix ONE 402 NRFit	45140251N- 01						
Perifix 420	4514203						
Perifix 421	4514211						
Perifix 430	4514300						
Perifix 431	4514319						
Perifix 620	4516206						
Perifix Soft Tip 900	4510291						
Perifix Soft Tip 901	4510305						
Perifix 421 NRFit	4514211N-01						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Perifix Soft Tip 901 NRFit	4510305N-01						
Perifix ONE 420	4514203C						
Perifix ONE 421	4514211C						
Perifix ONE 431	4514319C						
Perifix ONE Paed Set 18	4512006C						
Perifix ONE Paed Set 20	4512014C						
Perifix ONE 421 NRFit	4514211N-01						
Perifix ONE Paed Set 18 NRFit	45120061N-01						
Perifix ONE Paed Set 20 NRFit	45120141N-01						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Espocan	4556674	40392390000023862Y					
Espocan	4556666	G1 012974 0607; G7 012974 0612; NB0123					
Espocan with Docking System	4556747	TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123)					
Espocan with Docking System	4556763	TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123)					
Espocan NRFit	4556674N-01	2024-05-26					
Espocan NRFit	4556666N-01	2024-05-26					

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Espocan NRFit with Docking System	4556747N-01						
Espocan NRFit with Docking System	4556763N-01						
Certofix® Mono Paed S 110	4160177	403923900000007422J	G1 012974 0607;	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; NB0123	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	
Certofix® Mono Paed S 110	4160177-04						
Certofix® Mono S.215	4160185						

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Effective



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Article name	Article Number (under MDR application)						
Certofix [®] Mono S 215	4160185-07						
Certofix [®] Mono 215	4160185E						
Certofix [®] Mono 215	4160185E-07						
Certofix [®] Mono S 220	4160207						
Certofix [®] Mono S 220	4160207-07						
Certofix [®] Mono 220	4160207E						
Certofix [®] Mono 220	4160207E-07						
Certofix [®] Mono 220 R	4160207R						
Certofix [®] Mono V 220	4160215						
Certofix [®] Mono V 220	4160215-07						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix [®] Mono S 315	4160223						
Certofix [®] Mono S 315	4160223-07						
Certofix [®] Mono 315	4160223E						
Certofix [®] Mono 315	4160223E-07						
Certofix [®] Mono V 315	4160231						
Certofix [®] Mono V 315	4160231-07						
Certofix [®] Mono S 320	4160258						
Certofix [®] Mono S 320	4160258-07						
Certofix [®] Mono 320	4160258E						
Certofix [®] Mono 320	4160258E-07						

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Mono 320 R	4160258R						
Certofix® Safety Mono S 320	4160258S						
Certofix® Safety Mono S 320	4160258S-07						
Certofix® Mono V 320	4160266						
Certofix® Mono V 320	4160266-07						
Certofix® Mono S 330"	4160282						
Certofix® Mono S 330	4160282-07						
Certofix® Mono 330	4160282E						
Certofix® Mono 330"	4160282E-07						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Safety Mono S 330	4160282S						
Certofix® Safety Mono S 330	4160282S-07						
Certofix® Mono V 330	4160290						
Certofix® Mono V 330	4160290-07						
Certofix® Mono S 420"	4160304						
Certofix® Mono S 420"	4160304-07						
Certofix® Mono 420	4160304E						
Certofix® Mono 420	4160304E-07						

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Article name	Article Number (under MDR application)						
Certofix® Mono 420 R	4160304R						
Certofix® Mono V 420	4160320						
Certofix® Mono V 420	4160320-07						
Certofix® Mono S 415	4160509						
Certofix® Mono S 415	4160509-07						
Certofix® Mono 415	4160509E						
Certofix® Mono 415	4160509E-07						
Certofix® Mono V 415	4160517						
Certofix® Mono V 415	4160517-07						
Certofix® Trio HF S 1215	4160578						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Trio HF S 1215	4160578-07						
Certofix® Trio HF S 1220	4160586						
Certofix® Trio HF S 1220	4160586-07						
Certofix® Trio HF V 1215	4160614						
Certofix® Trio HF V 1215	4160614-07						
Certofix® Trio HF V 1220	4160622						
Certofix® Trio HF V 1220	4160622-07						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Mono S 430	4160762						
Certofix® Mono S 430	4160762-07						
Certofix® Mono 430	4160762E						
Certofix® Mono 430	4160762E-07						
Certofix® Mono V 430	4160789						
Certofix® Mono V 430	4160789-07						
Certofix® Trio 715	4161157E						
Certofix® Trio 715	4161157E-07						
Certofix® Trio S 715	4161159						
Certofix® Trio S 715	4161159-07						

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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Article name	Article Number (under MDR application)						
Certofix® Duo V 720	4161211						
Certofix® Duo V 720	4161211-07						
Certofix® Duo V 730	4161319						
Certofix® Duo V 730	4161319-07						
Certofix® Trio V 715	4162153						
Certofix® Trio V 715	4162153-07						
Certofix® Duo 720	4162200E						
Certofix® Duo 720	4162200E-07						
Certofix® Duo 730	4162307E						
Certofix® Duo 730	4162307E-07						

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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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Trio 720	4163206E						
Certofix® Trio 720	4163206E-07						
Certofix® Trio V 720	4163214						
Certofix® Trio V 720	4163214-07						
Certofix® Trio 730	4163303E						
Certofix® Trio 730	4163303E-07						
Certofix® Trio S 730	4163306						
Certofix® Trio S 730	4163306-07						
Certofix® Safety Trio S 730	4163306S						

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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Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Safety Trio S 730	4163306S-07						
Certofix® Trio V 730	4163311						
Certofix® Trio V 730	4163311-07						
Certofix® Duo 715	4164156E						
Certofix® Duo 715	4164156E-07						
Certofix® Duo S 715	4164158						
Certofix® Duo S 715	4164158-07						
Certofix® Duo V 715	4166159						
Certofix® Duo V 715	4166159-07						

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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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Quinto V 1215	4166841						
Certofix® Quinto V 1215	4166841-07						
Certofix® Quinto S 1220	4166852						
Certofix® Quinto S 1220	4166852-07						
Certofix® Safety Quinto S 1220	4166852S						
Certofix® Safety Quinto S 1220	4166852S-07						

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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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Quinto V 1220	4166868						
Certofix® Quinto V 1220	4166868-07						
Certofix® Duo Paed S 408	4166906						
Certofix® Duo Paed S 408	4166906-07						
Certofix® Duo Paed S 413	4166922						
Certofix® Duo Paed S 413	4166922-07						
Certofix® Duo Paed S 420	4166949						

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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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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Duo Paed S 420	4166949-07						
Certofix® Duo Paed S 508	4167112						
Certofix® Duo Paed S 508	4167112-07						
Certofix® Duo Paed S 513	4167139						
Certofix® Duo Paed S 513	4167139-07						
Certofix® Duo Paed S 520	4167155						
Certofix® Duo Paed S 520	4167155-07						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Trio Paed S 508	4167228						
Certofix® Trio Paed S 508	4167228-07						
Certofix® Trio Paed S 513	4167244						
Certofix® Trio Paed S 513	4167244-07						
Certofix® Trio Paed S 520	4167260						
Certofix® Trio Paed S 520	4167260-07						
Certofix® Duo S 720	4167385						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Duo S 720	4167385-07						
Certofix® Safety Duo S 720	4167385S						
Certofix® Safety Duo S 720	4167385S-07						
Certofix® Duo S 730	4167394						
Certofix® Duo S 730	4167394-07						
Certofix® Safety Duo S 730	4167394S						
Certofix® Safety Duo S 730	4167394S-07						
Certofix® Trio S 720	4167408						

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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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	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Trio S 720	4167408-07						
Certofix® Safety Trio S 720	4167408S						
Certofix® Safety Trio S 720	4167408S-07						
Certofix® Duo HF V 920	4167511						
Certofix® Duo HF V 920	4167511-07						
Certofix® Duo HF V 1215	4167538						
Certofix® Duo HF V 1215	4167538-07						

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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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	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® Duo HF V 1220	4167546						
Certofix® Duo HF V 1220	4167546-07						
Certofix® Quattro V 815	4167767						
Certofix® Quattro V 815	4167767-07						
Certofix® Quattro V 820	4167775						
Certofix® Quattro V 820	4167775-07						

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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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					Effect
Certofix [®] Safety Quattro V 820	4167775S						
Certofix [®] Safety Quattro V 820	4167775S-07						
Certofix [®] Quattro V 830	4167783						
Certofix [®] Quattro V 830	4167783-07						
Certofix [®] Duo HF V 715	4168518						
Certofix [®] Duo HF V 715	4168518-07						

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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Article name	Article Number (under MDR application)						
Certofix® Duo HF S 720	4168528	Basic UDI-DI (under MDR application)					
Certofix® Duo HF S 720	4168528-07						
Certofix® Duo HF V 720	4168534						
Certofix® Duo HF V 720	4168534-07						
Certofix® protect Mono V 320	4160266P	40392390000025883E	G1 012974 0607;	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; NB0123	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	

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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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	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® protect Mono V 330	4160290P						
Certofix® protect Mono V 330	4160290P-07						
Certofix® protect Mono V 420	4160320P						
Certofix® protect Mono V 420	4160320P-07						
Certofix® protect Trio HF V 1220	4160622P						
Certofix® protect Trio HF V 1220	4160622P-07						
Certofix® protect Mono V 430	4160789P						

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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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® protect Mono V 430	4160789P-07						
Certofix® protect Duo V 720	4161211P						
Certofix® protect Duo V 720	4161211P-07						
Certofix® protect Duo V 730	4161319P						
Certofix® protect Duo V 730	4161319P-07						
Certofix® protect Trio V 715	4162153P						
Certofix® protect Trio V 715	4162153P-07						

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Article name	Article Number (under MDR application)						
Certofix® protect Trio V 720	4163214P	Basic UDI-DI (under MDR application)					
Certofix® protect Trio V 720	4163214P-07						
Certofix® protect Trio V 730	4163311P						
Certofix® protect Trio V 730	4163311P-07						
Certofix® protect Duo V 715	4166159P						
Certofix® protect Duo V 715	4166159P-07						
Certofix® protect Duo V 715	4166159P-07						

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Certofix® protect Quinto V 1220	4166868P						
Certofix® protect Quinto V 1220	4166868P-07						
Certofix® protect Quattro V 815	4167767P						
Certofix® protect Quattro V 815	4167767P-07						
Certofix® protect Quattro V 820	4167775P						

Effective

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Article name	Article Number (under MDR application)						
Certofix® protect Quattro V 820	4167775P-07						
Certofix® protect Quattro V 830	4167783P						
Certofix® protect Quattro V 830	4167783P-07						
Certofix® protect Duo HF V 720	4168534P						
Certofix® protect Duo HF V 720	4168534P-07						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Spinocan®	4521801	403923900000008612T					
		G1 012974 0607;					
		G7 012974 0592; NB0123					
Spinocan®	4522001						4501373
Spinocan®	4522201						4509757
Spinocan®	4522202						4509900
Spinocan®	4522203						4507401
Spinocan®	4522204						4507754
Spinocan®	4522501						4507908
Spinocan®	4522502						4506090
Spinocan®	4522503						4505751
Spinocan®	4522601						4505905
Spinocan®	4522701						4505913
Spinocan®	4522702						4502906
							4504917
							4503902
							4502140

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Spinocan®	4522703						4501900
Spinocan®	4522901						4501918
Pencan	4532201						4502035
Pencan	4532501						4502167
Pencan	4532502						4502159
Pencan	4532503						4502019
Pencan	4532504						4502043
Pencan	4532506						4502116
Pencan	4532701						4502175
Pencan	4532702						4502027
Pencan	4532703						4502051
Pencan	4532705						4502124
Pencan	4532706						4502132
Atraucan®	4542601						4504771
Atraucan®	4542602						4504763
Atraucan®	4542603						4504739

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Article name	Article Number (under MDR application)						
Spinocan®	4521801N						4501390N-01
Spinocan®	4522001N						4501373N-01
Spinocan®	4522201N						4509757N-01
Spinocan®	4522202N						4509900N-01
Spinocan®	4522203N						4507401N-01
Spinocan®	4522204N						4507754N-01
Spinocan®	4522501N						4507908N-01
Spinocan®	4522502N						4506090N-01
							4506095N-01
							4505751N-01
							4505905N-01

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Article name	Article Number (under MDR application)						
Spinocan®	4522503N						4505913N-01
							4502906N-01
Spinocan®	4522601N						4504917N-01
Spinocan®	4522701N						4503902N-01
Spinocan®	4522702N						4502140N-01
							4501900N-01
Spinocan®	4522901N						4501901N-01
							4501918N-01
Pencan	4532201N						4502035N-01
Pencan	4532501N						4502167N-01
Pencan	4532502N						4502159N-01

Approval confirms: Correct document attached / complete document attached / scan is readable
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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

Effective

Schedule of Devices

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

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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	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Pencan	4532503N						4502019N-01
Pencan	4532504N						4502043N-01
Pencan	4532506N						4502044N-01
Pencan	4532507N						4502116N-01
Pencan	4532510N						4502117N-01
Pencan	4532701N						4502120N-01
Pencan	4532702N						333877N-01
							4502175N-01
							4502027N-01

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Article name	Article Number (under MDR application)						
Pencan	4532703N	4039239000000085938	G1 012974 0607; G7 012974 0592; NB0123	TÜV SÜD Product Service GmbH (NB0123) TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	4502051N-01
Pencan	4532705N						4502052N-01
Pencan	4532706N						4502124N-01
Pencan	4502035-13					2027-12-31	4502125N-01
Pencan	4502167-13						4502132N-01
Pencan	4502159-13						N/A
Pencan	4502019-01						
Pencan	4502019-10						
Pencan	4502043-13						
Pencan	4502116-13						
Pencan	4502120-13						

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Pencan	4502175-13						
Pencan	4502027-01						
Pencan	4502027-10						
Pencan	4502051-13						
Pencan	4502124-13						
Pencan	4502132-13						
Spinocan®	4501373-13						
Spinocan®	4501390-01						
Spinocan®	4501390-10						
Spinocan®	4501144-13						
Spinocan®	4501195-13						
Spinocan®	4509757-13						
Spinocan®	4509900-01						
Spinocan®	4509900-10						
Spinocan®	4507401-13						
Spinocan®	4507754-13						
Spinocan®	4507908-01						
Spinocan®	4507908-10						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
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						
Perican	4512453	40392390000023912R					
		G1 012974 0607;	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Perican	4512200						
Perican	4512383						
Perican	4512588						
Perican	4512782						
Perican Paed	4502078						
Perican Paed	4502094						
Perican Paed	4502302						
Perican NRFit	4512383N-01						
Perican NRFit	4512200N-01						
Perican NRFit	4512782N-01						
Perican NRFit	4512453N-01						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Perican NRFit	4512785N-01						
Perican NRFit	4512784N-01						
Perican Paed NRFit	4502078N-01						
Perican Paed NRFit	4502094N-01						
Perican Paed NRFit	4502302N-01						
Epican Paed	4502400	403923900000027953M	G1 012974 0607;	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	N/A
Epican Paed	4502418		G7 012974 0612; NB0123	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2027-12-31	
Epican Paed	4502426						
Epican Paed NRFit	4502400N-01						
Epican Paed NRFit	4502418N-01						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Epican Paed NRFit	4502426N-01							

Effective

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Document History

Version	Description of Change
1.0	Initial version

Effective

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

B. Braun Melsungen AG - Document No.: G12 - Version: 1.0 - Document ID: RE-QM-DIV-000445 - Effective Date: 2024-05-06
Title: BBWAG_LM_confirmation letter_Regulation EU 2023/607_G12

UserName: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: Monday, 29 April 2024, 15:05 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 29 April 2024, 15:41 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 30 April 2024, 10:49 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Thursday, 02 May 2024, 09:18 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Monday, 06 May 2024, 07:01 W. Europe Daylight Time
Meaning: Approve Document
=====

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:

UserName: Meyer, Frank (meyefrde)
Title: HC-QM-DE08 Vice President QM Applications Hospital Care
Date: Monday, 06 May 2024, 12:52 W. Europe Daylight Time
Meaning: Final Release of the Document
=====

B. Braun Melsungen AG - Document No.: G12 - Version: 1.0 - Document ID: RE-QM-DIV-000445 - Effective Date: 2024-05-06
Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G12

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