B BRAUN
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 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.

B|BRAUN
SHARING EXPERTISE

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) G2MS 012974 0456 Rev.01; (3) G2S 012974 0457 Rev.02; (4) G2S 019717 0033 Rev.00	☒ 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	2028-12-31	☒ 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	**Thomas Brand**	**Dr. Stefan Seidel**
Title	**Vice President Quality Management for non-active Medical Devices**	**Head of Regulatory Affairs CoE Infusion & Pain Therapy**
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)**
4616005	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Omnifix® Slip
U2040532	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Mini Redovac® 50
4090500	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Transofix®
4090500IN							Transofix®
4637100	G2S 012974 0457 Rev. 02	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Perifix® LOR
4638107							Perifix® LOR
4637110							Perifix® LOR NRFIT
4638110							Perifix® LOR NRFIT
4511200	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Perifix® Catheter Fixation
4511201	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Perifix® Catheter Fixation Cover

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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4417910	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Ureofix® 500 Classic
4417920							Ureofix® 500 Classic
4417930							Ureofix® 500 Classic
4417940							Ureofix® 500 Classic
4417950							Ureofix® 500 Classic
4417960							Ureofix® 500 Classic
4417535	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Ureofix® 500 Classic
4417543							Ureofix® 500 Classic
4417551							Ureofix® 500 Classic
A1687	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Cyto-Set(R) Infusion
A1686SNF	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Cyto-Set(R) Infusion
A1687SNF							Cyto-Set(R) Infusion

Effective

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A1688							Cyto-Set(R) Infusion
8258813	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Aspiration Needle
4190050	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	4190060	Aeration Needle
4606970	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Exadoral®
4606975							Exadoral®
4608680							Exadoral®
4099206	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Sterifix® 0.2 µm
4462009	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Secretion Bag
4606960	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Exadoral®
4606962							Exadoral®
4606963							Exadoral®
4606967							Exadoral®
4608660							Exadoral®

Effective

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4608661							Exadoral®
4608662							Exadoral®
4608663							Exadoral®
4608667							Exadoral®
4609660							Exadoral®
4609662							Exadoral®
4609663							Exadoral®
4609667							Exadoral®
9166408V	G1 012974 0607 Rev. 02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Injekt® 40 Solo
4517501N	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Syringe Cap NRFit®
4517502N							Stopper NRFit®
4550590	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Mini-Spike® 2
4550591							Mini-Spike® 2 Filter
4550592							Mini-Spike® 2 Chemo
4550593							Mini-Spike® 2 Micro-Tip

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4550594							Mini-Spike® 2 Filter Micro-Tip
4550595							Mini-Spike® 2 Chemo Micro-Tip
4550315	G2S 012974 0457 Rev. 02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Mini Spike® Plus 6/8 R
4037035	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Dosifix®
4063007	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Intrafix® SafeSet
9240625 9240626 9240632 9240669 9240677 9240678 9240679	G2S 019717 0033 Rev.00; NB0123 B. Braun Avitum Italy S.p.A.	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)	2028-12-31	9240627	Nutrifix® ENFit® Set

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9240680 9240685 9240800							
9240621 9240622 9240623 9240624						9240620	Nutrifix® ENFit® Set
4052480	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Intrafix® Primeline
4060369							Intrafix® Primeline
4062181							Intrafix® Primeline
4062191							Intrafix® Primeline
4063002							Intrafix® SafeSet
4063008							Intrafix® SafeSet
4063009							Intrafix® SafeSet
4063020							Intrafix® SafeSet

Effective

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4063100							Intrafix® SafeSet
4064007							Intrafix® Primeline
4064008							Intrafix® Primeline
4064009							Intrafix® Primeline
4064100							Intrafix® Primeline
4099842N							Intrapur® Inline
4110020							Intrafix® SafeSet
4187890							ProSet Intrafix® SafeSet
4188587							ProSet Intrafix®
0086774R	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Intrafix® Primeline
4063131							Intrafix® SafeSet
4062191CN	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Primeline
4063002CN							SafeSet
4037036	G2MS 012974 0456 Rev.01;	2024-05-26	TÜV SÜD Product Service GmbH	TÜV SÜD Product Service GmbH	2028-12-31	N/A	Dosifix®

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4037037	0456 Rev.01; NB0123		Service GmbH (NB0123)	Service GmbH (NB0123)			Dosifix®
4037038							Dosifix®
4037033	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Dosifix®
4037034							Dosifix®
4037016	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Dosifix®
4037039							Dosifix®
4061209	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Exadrop®
4061225							Exadrop®
4061276							Exadrop®
4061284							Exadrop®
4062264							Exadrop®
4180330							Exadrop®
4186719							Exadrop®
4186720							Exadrop®
4188144							Exadrop®
4061306	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Exadrop®
9161309V	G1 012974 0607 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH	TÜV SÜD Product Service GmbH	2028-12-31	N/A	Omnifix® 40 Solo

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9161708V			(NB0123)	(NB0123)			Omnifix® 100 Solo
4616022V	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Omnifix® Luer Solo
4616025V							Omnifix® Luer Solo
4616050V							Omnifix® Luer Solo
4616057V							Omnifix® Luer Solo
4616103V							Omnifix® Luer Solo
4616107V							Omnifix® Luer Solo
4616200V							Omnifix® Luer Solo
4616200V-03							Omnifix® Luer Solo
4616308F							Omnifix® Luer Solo
4616502F							Omnifix® Luer Solo
9161406V							Omnifix®-F Luer Solo

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4617029LDS	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Omnifix® Luer Lock Solo
9167006V							Omnifix®-F Luer Lock Solo
9162607V	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Omnifix®-H Luer Solo
9162909V							Omnifix®-H Luer Solo
4038088-01	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Sterican® MIX
4038088-03							Sterican® MIX
4550400-01							Sterican® MIX
4550400-03							Sterican® MIX
4550400-04							Sterican® MIX
4606065	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	5 ml Syringe ALDO Union Oral Dispenser

[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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4606925							3 ml Apirofeno Oral Dispenser FOR ORAL USE
4606940							5 ml Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE
4606945							5 ml Dispensador Oral (6 mg/3 mL) FOR ORAL USE NON-STERILE
4606950							5 ml Farmalider Oral Dispenser FOR ORAL USE
4606951							5 ml Farmalider, IBUPROM FOR ORAL USE

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4606952							2 mL Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE
4606954							5ml APAP® Oral Dispenser FOR ORAL USE
4606972							5 ml Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE
4606980							5 ml Apiretal Oral Dispenser FOR ORAL USE
4606985							5 ml Apirofeno Oral Dispenser FOR ORAL USE

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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 (MDR Application)**
4607040							10 ml Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE
4608961							1 mL Dispenser Lacovin®
4550242	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Mini-Spike®
4550234							Mini-Spike® Filter
4550340							Mini-Spike® Chemo
4550340-04							Mini-Spike® Chemo
4550510							Mini-Spike® Micro-Tip
4550528							Mini-Spike® Filter Micro-Tip
4550536							Mini-Spike® Chemo Micro-Tip
4550560							Mini-Spike® V

Effective

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Effective

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 (MDR Application)**
4550560-04							Mini-Spike® V
4550560IN							Mini-Spike® V
4550579							Mini-Spike® Filter V
4550579-04							Mini-Spike® Filter V
4550587							Mini-Spike® Chemo V
4550587-04							Mini-Spike® Chemo V
4090549	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Ecoflac® Connect
4090550							Ecoflac® Connect
4090552							Ecoflac® Connect
16401	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	16401N	Ecoflac® Mix
9166106V	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Injekt®-H Luer Solo
9166203V							Injekt®-H Luer Solo
9166254V							Injekt®-H Luer Solo

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 (MDR Application)**
4606027V	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Injekt® Luer Solo
4606027V-03	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Injekt® Luer Solo
4606051V							Injekt® Luer Solo
4606051V-03							Injekt® Luer Solo
4606058							PP 5,3 ml Luer Solo
4606108V							Injekt® Luer Solo
4606108V-03							Injekt® Luer Solo
4606205V							Injekt® Luer Solo
4606205V-03							Injekt® Luer Solo
9161450							AS Plus Luer Solo 1 ml
9166017V							Injekt®-F Luer Solo
NJ-4606027							NORM-JECT® Luer Solo

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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 (MDR Application)**
NJ-4606051							NORM-JECT® Luer Solo
NJ-4606108							NORM-JECT® Luer Solo
NJ-4606110							NORM-JECT® Luer Solo
NJ-4606205							NORM-JECT® Luer Solo
NJ-4606027-02							NORM-JECT® Luer Solo
NJ-4606051-02							NORM-JECT® Luer Solo
NJ-4606067-02							NORM-JECT® Luer Solo
NJ-4606108-02							NORM-JECT® Luer Solo
NJ-4606205-02							NORM-JECT® Luer Solo
NJ-9166017-02							NORM-JECT®-F Luer Solo
4606701V	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Injekt® Luer Lock Solo
4606710V							Injekt® Luer Lock Solo
4606728V							Injekt® Luer Lock Solo

Effective

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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 (MDR Application)**
4606736V							Injekt® Luer Lock Solo
NJ-4606701-02							NORM-JECT® Luer Lock Solo
NJ-4606710-02							NORM-JECT® Luer Lock Solo
NJ-4606728							NORM-JECT® Luer Lock Solo
NJ-4606728-02							NORM-JECT® Luer Lock Solo
NJ-4606736-02							NORM-JECT® Luer Lock Solo
NJ-4606755BMS							NORM-JECT® Luer Lock Solo
4613503F	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Omnifix®
4616003	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Omnifix® Slip
4616014							Omnifix® Slip
4616021							Omnifix® Slip
9164001							Omnifix®-F Slip
8258821	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	Aspiration Needle

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4600190C	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	4 ML DISPENSER SET „DO NOT RINSE“
4600238C							1 ML DISPENSER-SET
4606744C							4 ML DISPENSER-SET „6 MG PROMETAX“®
4606957C							4 ML DISPENSER-SET “6 MG EXELON”®
4606958R							4 ml Dispenser-Set “6mg”
4600096C	G2MS 012974 0456 Rev.01; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A	4ML DISPENSER-SET / 93 MM
4600096S							4 ml Dispenser-Set with Suction Tube 93 mm FOR ORAL USE

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4600185C							4 ML DISPENSER SET „DO NOT RINSE“ / 93 MM
4600231C							1 ML DISPENSER SET / 93 MM
4600231S							1 ml Dispenser-Set with Suction Tube 93 mm FOR ORAL USE
4600235C							1 ML DISPENSER-SET / 93 MM
4600250C							NEORAL 1 ml Oral Dispenser Pipette Graduee Neoral 1 ml FR
4600255C							Neoral 4 ml Oral Dispenser Pipette Graduee Neoral 4 ml FR

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4600260C							Sandimmun 1 ml Oral Dispenser Pipette Graduee Sandimmun 1 ml FR
4600265C							Sandimmun 4 ml Oral Dispenser Pipette Graduee Sandimmun 4 ml FR
4600269C							1 ml Dispenser-Set with Suction Tube 93 mm FOR ORAL USE SANDIMMUN or SANDIMMUN NEORAL

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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

Title: BBMAG_LM_confirmation letter_ Regulation EU 2023_607_G11 Initiator: Anja Mai

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, 17:12 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, 17:20 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, 09:59 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Meyer, Frank (meyefrde)
Title: HC-QM-DE08 Vice President QM Applications Hospital Care
Date: Monday, 05 August 2024, 08:19 W. Europe Daylight Time
Meaning: Final Release of the Document
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