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) 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, 2024-05-17**	**Melsungen, 2024-05-17**
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 2.0**	

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	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnifix® Slip	4616005	403923900000026423	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
Mini Redovac® 50	U2040532	40392390000002852B	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®	4090500	4039239000000271ZV	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							
Perifix® LOR	4637100	403923900000238936	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 NRFIT	4637110							
Perifix® LOR NRFIT	4638110							
Perifix® Catheter Fixation	4511200	40392390000023852W	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	4511201	4039239000002 7943K	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

[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)**	**Basic UDI-DI (under MDR application)**						
Ureofix® 500 Classic	4417910	403923900000018526	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	403923900000018628	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							
Cyto-Set(R) Infusion	A1687	403923900000026729	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	403923900000026729	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							

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set(R) Infusion	A1688							
Aspiration Needle	8258813	40392390000023812N	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
Aeration Needle	4190060	40392390000002892K	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	4190050
Exadoral®	4606970	40392390000002872F	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							
Sterifix® 0.2 µm	4099206	40392390000027426	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	4462009	40392390000000280ZW	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
Exadoral®	4606960	40392390000002862D	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							

[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)	Basic UDI-DI (under MDR application)						
Exadoral®	4608661							
Exadoral®	4608662							
Exadoral®	4608663							
Exadoral®	4608667							
Exadoral®	4609660							
Exadoral®	4609662							
Exadoral®	4609663							
Exadoral®	4609667							
Injekt® 40 Solo	9166408V	4039239000001220ZK	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
Syringe Cap NRFit®	4517501N	40392390000023902P	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
Stopper NRFit®	4517502N							
Mini-Spike® 2	4550590	4039239000000270ZT	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 Filter	4550591							
Mini-Spike® 2 Chemo	4550592							
Mini-Spike® 2 Micro-Tip	4550593							

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Article name	**Article Number (under MDR application)**	**Basic UDI-DI (under MDR application)**						
Mini-Spike® 2 Filter Micro-Tip	4550594							
Mini-Spike® 2 Chemo Micro-Tip	4550595							
Mini Spike® Plus 6/8 R	4550315	40392390000027212Q	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
Dosifix®	4037035	40392390000002942C	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
Intrafix® SafeSet	4063007	403923900000026525	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
Nutrifix® ENFit® Set	9240627	403923900000263834	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	9240625 9240626 9240632 9240669 9240677 9240678 9240679

[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)						
								9240680 9240685 9240800
Nutrifix® ENFit® Set	9240620							9240621 9240622 9240623 9240624
Intrafix® Primeline	4052480	403923900000026525	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® SafeSet	4063002							
Intrafix® SafeSet	4063008							
Intrafix® SafeSet	4063009							
Intrafix® SafeSet	4063020							

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Article name	**Article Number (under MDR application)**	**Basic UDI-DI (under MDR application)**						
Intrafix® SafeSet	4063100							
Intrafix® Primeline	4064007							
Intrafix® Primeline	4064008							
Intrafix® Primeline	4064009							
Intrafix® Primeline	4064100							
Intrapur® Inline	4099842N							
Intrafix® SafeSet	4110020							
ProSet Intrafix® SafeSet	4187890							
ProSet Intrafix®	4188587							
Intrafix® Primeline	0086774R	40392390000014812L	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	4063131							
Primeline	4062191CN	403923900000026627	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
SafeSet	4063002CN							

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Schedule of Devices

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Dosifix®	4037036	40392390000002942C	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®	4037037							
Dosifix®	4037038							
Dosifix®	4037033	40392390000026052M	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	40392390000024302A	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							
Exadrop®	4061209	40392390000002692D	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	40392390000025902Z	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

[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)						
Omnifix® 40 Solo	9161309V	403923900000121925	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
Omnifix® 100 Solo	9161708V							
Omnifix® Luer Solo	4616022V	4039239000000261ZS	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							

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnifix®-F Luer Solo	9161406V							
Omnifix® Luer Lock Solo	4617029LDS	4039239000000262ZU	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®-F Luer Lock Solo	9167006V							
Omnifix®-H Luer Solo	9162607V	4039239000000263ZW	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							
Sterican® MIX	4038088-01	403923900000025726	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							
5 ml Syringe ALDO Union Oral Dispenser	4606065	40392390000002872F	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

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

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

[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)**						
10 ml Oral Dispenser Dosificador Oral – NORMON FOR ORAL USE NON-STERILE	4607040							
1 mL Dispenser Lacovin®	4608961							
Mini-Spike®	4550242	4039239000000270ZT	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® Filter	4550234							
Mini-Spike® Chemo	4550340							
Mini-Spike® Chemo	4550340-04							
Mini-Spike® Micro-Tip	4550510							
Mini-Spike® Filter Micro-Tip	4550528							
Mini-Spike® Chemo Micro-Tip	4550536							
Mini-Spike® V	4550560							

[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	**Article Number (under MDR application)**	**Basic UDI-DI (under MDR application)**						
Mini-Spike® V	4550560-04							
Mini-Spike® V	4550560IN							
Mini-Spike® Filter V	4550579							
Mini-Spike® Filter V	4550579-04							
Mini-Spike® Chemo V	4550587							
Mini-Spike® Chemo V	4550587-04							
Ecoflac® Connect	4090549	403923900000027324	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® Mix	16401N	403923900000027222	G2S 012974 0457 Rev.02; NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	16401
Injekt®-H Luer Solo	9166106V	40392390000002592A	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							

[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)**						
Injekt® Luer Solo	4606027V	40392390000007732V	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	40392390000007732V	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							
PP 5,3 ml Luer Solo	4606058							
Injekt® Luer Solo	4606108V							
Injekt® Luer Solo	4606108V-03							
Injekt® Luer Solo	4606205V							
Injekt® Luer Solo	4606205V-03							
AS Plus Luer Solo 1 ml	9161450							
Injekt®-F Luer Solo	9166017V							
NORM-JECT® Luer Solo	NJ-4606027							

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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	**Article Number (under MDR application)**	**Basic UDI-DI (under MDR application)**						
NORM-JECT® Luer Solo	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®-F Luer Solo	NJ-9166017-02							
Injekt® Luer Lock Solo	4606701V	4039239000000260ZQ	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							

[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)**						
Injekt® Luer Lock Solo	4606736V							
NORM-JECT® 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							
Omnifix®	4613503F	403923900000029126	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	4616003	403923900000026423	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®-F Slip	9164001							
Aspiration Needle	8258821	40392390000023822Q	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

[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

Effective

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	**Article Number (under MDR application)**	**Basic UDI-DI (under MDR application)**						
4 ML DISPENSER SET „DO NOT RINSE“	4600190C	40392390000002872F	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
1 ML DISPENSER-SET	4600238C							
4 ML DISPENSER-SET „6 MG PROMETAX“®	4606744C							
4 ML DISPENSER-SET “6 MG EXELON”®	4606957C							
4 ml Dispenser-Set “6mg”	4606958R							
4ML DISPENSER-SET / 93 MM	4600096C	403923900000029024	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 with Suction Tube 93 mm FOR ORAL USE	4600096S							

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

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	**Article Number (under MDR application)**	**Basic UDI-DI (under MDR application)**						
4 ML DISPENSER SET „DO NOT RINSE" / 93 MM	4600185C							
1 ML DISPENSER SET / 93 MM	4600231C							
1 ml Dispenser-Set with Suction Tube 93 mm FOR ORAL USE	4600231S							
1 ML DISPENSER-SET / 93 MM	4600235C							
NEORAL 1 ml Oral Dispenser Pipette Graduee Neoral 1 ml FR	4600250C							
Neoral 4 ml Oral Dispenser Pipette Graduee Neoral 4 ml FR	4600255C							

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Schedule of Devices

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Article name	**Article Number (under MDR application)**	**Basic UDI-DI (under MDR application)**						
Sandimmun 1 ml Oral Dispenser Pipette Graduee Sandimmun 1 ml FR	4600260C							
Sandimmun 4 ml Oral Dispenser Pipette Graduee Sandimmun 4 ml FR	4600265C							
1 ml Dispenser-Set with Suction Tube 93 mm FOR ORAL USE SANDIMMUN or SANDIMMUN NEORAL	4600269C							

[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

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: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: Friday, 17 May 2024, 14:37 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Friday, 17 May 2024, 15:38 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Friday, 17 May 2024, 15:59 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Meyer, Frank (meyefrde)
Title: HC-QM-DE08 Vice President QM Applications Hospital Care
Date: Tuesday, 21 May 2024, 13:37 W. Europe Daylight Time
Meaning: Final Release of the Document
==========