

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) G1 019717 0032; (3) G1 022239 0080; (4) G2S 012974 0457	<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	2028-12-31	<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) Mareike Arico; (3) Dr. Frank Ritz	(4) Dr. Stefan Seidel; (5) Malte Loh; (6) Dr. Joachim Buenger
Title	(1) Vice President Quality Management for non-active Medical Devices; (2) Head of Quality Management Active Medical Devices/ Head of	(4) Head of Regulatory Affairs CoE Infusion & Pain Therapy; (5) Senior Manager Regulatory



	Regulatory Affairs CoE AIS; (3) Vice President QM Pharma; Hospital Care Division	Affairs; (6) Director Template & Submission Mgmt
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.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 -
Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10

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)						
Perfusor® compactplus	8717030	40392390000000038ZM	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus	8717050	403923900000005352B	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
OnlineSuite	876100	403923900000005552H	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Perfusor®	8719030	403923900000007562V	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Infusomat®	8719050	403923900000007552T	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus P	8717070	403923900000007482Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4116011F	40392390000000039ZP	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617006	40392390000000044ZG	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	932M04SE	40392390000018743B	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	931M08SE		NB0123		TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainbag® 600 V	5523606	403923900000007973B	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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)	403923900000169539	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drug Library Manager Spaceplus	876203						
Drug Library Manager Spaceplus	876209	403923900000169539	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FR29914						
GLYCINE 1,5 % B. BRAUN	FREU914	403923900000249638	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FREU934						
GLYCINE 1,5 % B. BRAUN	FREU954	403923900000250128	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FREU974						
NaCl 0.9 % B. BRAUN	FREU850	40392390000026312N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	FREU910						
NaCl 0.9 % B. BRAUN	FREU930	40392390000026312N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	FREU950						
NaCl 0.9 % B. BRAUN	FREU970	40392390000026312N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	3570100						
NaCl 0.9 % B. BRAUN	3637006	40392390000026312N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	0069414E						
NaCl 0.9 % B. BRAUN	3521360	40392390000026312N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	3570120						

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)	G1 012974 0607 NB0123 4039239000025022A					
NaCl 0.9 % B. BRAUN	3570130						
NaCl 0.9 % B. BRAUN	3570140						
NaCl 0.9 % B. BRAUN	0066570E						
NaCl 0.9 % B. BRAUN	3521370						
NaCl 0.9 % B. BRAUN	3570150						
NaCl 0.9 % B. BRAUN	3570160						
NaCl 0.9 % B. BRAUN	3570170						
NaCl 0.9 % B. BRAUN	0066569E						
NaCl 0.9 % B. BRAUN	3570110						
Vitulia	450268						
Vitulia	450272						
NaCl 0.9 % B. BRAUN	3570300						
NaCl 0.9 % B. BRAUN	3570301						
NaCl 0.9 % B. BRAUN	3570310						
NaCl 0.9 % B. BRAUN	3570330						
NaCl 0.9 % B. BRAUN	391858						
NaCl 0.9 % B. BRAUN	3570350						
NaCl 0.9 % B. BRAUN	3570360						
NaCl 0.9 % B. BRAUN	3570340						
NaCl 0.9 % B. BRAUN	3637010						
NaCl 0.9 % B. BRAUN	391859						

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Article name	Article Number (under MDR application)						
NaCl 0.9 % B. BRAUN	3570370						N/A
NaCl 0.9 % B. BRAUN	3570380						N/A
NaCl 0.9 % B. BRAUN	3570390						N/A
NaCl 0.9 % B. BRAUN	391860						N/A
NaCl 0.9 % B. BRAUN	3570410						N/A
NaCl 0.9 % B. BRAUN	3570420						N/A
NaCl 0.9 % B. BRAUN	3570460	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	3570470	NB0123					N/A
NaCl 0.9 % B. BRAUN	3570480						N/A
RINGER B. BRAUN	FREU984	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	FREU924	NB0123					FREU920
RINGER B. BRAUN	FREU944						N/A
RINGER B. BRAUN	FREU964						N/A
RINGER B. BRAUN	FREU984						N/A
RINGER B. BRAUN	3570000	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	3570010	NB0123					N/A
RINGER B. BRAUN	3570020						N/A
RINGER B. BRAUN	3570030						N/A
RINGER B. BRAUN	3570040						N/A
RINGER B. BRAUN	3570050						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)						
RINGER B. BRAUN	3570060							N/A
RINGER B. BRAUN	3570611	40392390000026322Q	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570490
RINGER B. BRAUN	3570610							3570500
RINGER B. BRAUN	3570614							3570510
RINGER B. BRAUN	3570612							3570520
RINGER B. BRAUN	3570613	40392390000026332S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570530
Aqua B. Braun	FREU812	40392390000024973A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	FREU852							N/A
Aqua B. Braun	FREU912							N/A
Aqua B. Braun	FREU932							N/A
Aqua B. Braun	387872	40392390000026272X	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	387873							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	387874	4039239000000262933						
Aqua B. Braun	442464							
Aqua B. Braun	442465							
Aqua B. Braun	442466							
Sterile Water for Irrigation	3637011							
Aqua B. Braun	3521380	4039239000000238732						
Aqua B. Braun	3521390							
Aqua B. Braun	3553949							
Aqua B. Braun	3553957							
Aqua B. Braun	0065729E							
Aqua B. Braun	0066571E							
Aqua B. Braun	0069415E							
Aqua B. Braun	0082423E	403923900000007462S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123) <th rowspan="7">N/A</th>	N/A	
Aqua B. Braun	0082479E							
Sterile Water for Irrigation	3637007							
Perifix® Catheter Connector	4513800							
Perifix® Catheter Connector	4513801							
Perifix® Catheter Connector NRFit	4513800N-01							
Perifix® Catheter Connector NRFit	4513801N-01							
Infusomat® Space	8713050	403923900000007462S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space P	8713070						
Perfusor® Space	8713030	40392390000007482W	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Enteroport® plus	8710355	40392390000007452Q	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200	403923900000008622V	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200+20						
Infusomat® Plus Line SafeSet	8700210						
Infusomat® Plus Line	8700310						
Infusomat® Plus Line	8700310+20						
Infusomat® Plus Line	8700310CN						
Cyto-Set® Infusomat® Space	8250414SP	40392390000007832Y	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Infusomat® Space	8250817SP						
Cyto-Set® Infusomat® Space	8250820SP						
Cyto-Set® Infusomat® Space	8250917SP						
Cyto-Set® Infusomat® Space	8250920SP						
Cyto-Set® Infusomat® Space	8250920SP						

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)						
Cyto-Set® Infusomat® Space	835414SP						
Cyto-Set® Infusomat® Space	835817SP						
Cyto-Set® Infusomat® Space	835820SP						
Cyto-Set® Infusomat® Space	835917SP						
Cyto-Set® Infusomat® Space	835920SP						
Cyto-Set® Infusomat® plus	8700420						
Cyto-Set® Infusomat® plus	8700430						
Cyto-Set® Infusomat® plus	8700440						
Cyto-Set® Infusomat® plus	8700450						
Cyto-Set® Infusomat® plus	8700460						
Cyto-Set® Infusomat® plus	8700470						
Cyto-Set® Infusomat® plus	8700480						
Cyto-Set® Infusomat® plus	8700490						
Cyto-Set® Line	A2581NF		G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Line	A2582NF		NB0123				N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set® Mix	A2900N	40392390000008602R	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Mix	A2903N							N/A
Cyto-Set® Mix	A2906N							N/A
Cyto-Set® Mix	A2907N							N/A
Cyto-Set® Mix	A2908N							N/A
Stimuplex® A	4894251							N/A
Stimuplex® A	4894539							N/A
Stimuplex® A	4894367							N/A
Stimuplex® A	4894502							N/A
Stimuplex® A	4894375							N/A
Stimuplex® A	4894260							N/A
Stimuplex® A	4894278							N/A
Stimuplex® A	4894278NR							N/A
Stimuplex® A	4894375NR							N/A
Stimuplex® A	4894260NR							N/A
Stimuplex® A	4894367NR	40392390000023452J	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® A	4894539NR							N/A
Stimuplex® A	4894502NR							N/A
Easypump® II LT 60-12	4540002							N/A
Easypump® II LT 60-12	4540002-07							N/A
Easypump® II LT 60-12	4540002-20							N/A
Easypump® II LT 500-12.5	4540003							N/A
Easypump® II LT 500-12.5	4540003-07							N/A
Easypump® II LT 500-12.5	4540003-20							N/A
Easypump® II LT 80-16	4540004							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 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)						
Easypump® II LT 80-16	4540004-07							N/A
Easypump® II LT 80-16	4540004-20							N/A
Easypump® II LT 125-25	4540006							N/A
Easypump® II LT 125-25	4540006-07							N/A
Easypump® II LT 125-25	4540006-20							N/A
Easypump® II LT 270-27	4540008							N/A
Easypump® II LT 270-27	4540008-07							N/A
Easypump® II LT 270-27	4540008-20							N/A
Easypump® II LT 60-30	4540010							N/A
Easypump® II LT 60-30	4540010-07							N/A
Easypump® II LT 60-30	4540010-20							N/A
Easypump® II LT 120-30	4540012							N/A
Easypump® II LT 120-30	4540012-07							N/A
Easypump® II LT 120-30	4540012-20							N/A
Easypump® II LT 400-40	4540014							N/A
Easypump® II LT 400-40	4540014-07							N/A
Easypump® II LT 400-40	4540014-20							N/A
Easypump® II LT 100-50	4540016							N/A
Easypump® II LT 100-50	4540016-07							N/A
Easypump® II LT 100-50	4540016-20							N/A
Easypump® II LT 270-54	4540018							N/A

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Article name	Article Number (under MDR application)						
Easypump® II LT 270-54	4540018-07						
Easypump® II LT 270-54	4540018-20						N/A
Easypump® II LT 400-80	4540022						N/A
Easypump® II LT 400-80	4540022-07						N/A
Easypump® II LT 400-80	4540022-20						N/A
Easypump® II LT 270-68	4540026						N/A
Easypump® II LT 270-68	4540026-07						N/A
Easypump® II LT 270-68	4540026-20						N/A
Easypump® II LT 400-100	4540028						N/A
Easypump® II LT 400-100	4540028-07						N/A
Easypump® II LT 400-100	4540028-20						N/A
Easypump® II LT 270-135	4540032						N/A
Easypump® II LT 270-135	4540032-07						N/A
Easypump® II LT 270-135	4540032-20						N/A
Easypump® II ST 100-0.5	4540040						N/A
Easypump® II ST 100-0.5	4540040-20						N/A
Easypump® II ST 250-0.5	4540042						N/A
Easypump® II ST 250-0.5	4540042-07						N/A
Easypump® II ST 230-0.5	4540042-20						N/A
Easypump® II ST 50-1	4540044						N/A

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Article name	Article Number (under MDR application)						
Easypump® II ST 50-1	4540044-07						
Easypump® II ST 50-1	4540044-20						N/A
Easypump® II ST 100-1	4540046						N/A
Easypump® II ST 100-1	4540046-07						N/A
Easypump® II ST 100-1	4540046-20						N/A
Easypump® II ST 250-1	4540048						N/A
Easypump® II ST 250-1	4540048-07						N/A
Easypump® II ST 250-1	4540048-20						N/A
Easypump® II ST 250-1.5	4540050						N/A
Easypump® II ST 250-1.5	4540050-07						N/A
Easypump® II ST 250-1.5	4540050-20						N/A
Easypump® II ST 400-2	4540052						N/A
Easypump® II ST 400-2	4540052-07						N/A
Easypump® II ST 400-2	4540052-20						N/A
Easypump® II ST 500-2	4540054						N/A
Easypump® II ST 500-2	4540054-07						N/A
Easypump® II ST 500-2	4540054-20						N/A
Easypump® II ST 100-2	4540056						N/A
Easypump® II ST 100-2	4540056-07						N/A

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Article name	Article Number (under MDR application)	403923900000085836	G1 012974 0607				N/A
Easyump® II ST 100-2	4540056-20						
Easyump® II ST 400-4	4540058						
Easyump® II ST 400-4	4540058-07						
Easyump® II ST 400-4	4540058-20	403923900000085836	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	4505000
Spinal Introducer	4505000-13						
Spinal Introducer	4500059-13	NB0123	NB0123				4500059
Contiplex® S 360	4898650CN	40392390000008542W	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® S 360	4898610CN						
Contiplex® S 360	4898615CN						
Contiplex® S Ultra 360®	4898650-01						
Contiplex® S Ultra 360®	4898610-01						
Contiplex® S Ultra 360®	4898615-01						
Contiplex® S Ultra 360®	4898650-27						
Contiplex® S Ultra 360®	4898610-27						
Contiplex® S Ultra 360®	4898615-27						
Contiplex® S Ultra 360®	4898615-27						
Perifix® Filter	4515501	403923900000238834	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Filter	4515501N-01						

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Article name	Article Number (under MDR application)	403923900000008542W NB0123	G1 012974 0607 NB0123	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	
Contiplex® S Ultra 360® NRFit®	4898650NR-27						
Contiplex® S Ultra 360® NRFit®	4898610NR-27						
Contiplex® S Ultra 360® NRFit®	4898615NR-27						
Contiplex® Tuohy Ultra 360® NRFit®	4898704NR-01						
Contiplex® Tuohy Ultra 360® NRFit®	4898705NR-01						
Contiplex® Tuohy Ultra 360® NRFit®	4898710NR-01						
Contiplex® Tuohy Ultra 360® NRFit®	4898715NR-01						
Contiplex® Tuohy Ultra 360®	4898704-01						
Contiplex® Tuohy Ultra 360®	4898705-01						
Contiplex® Tuohy Ultra 360®	4898710-01						
Contiplex® Tuohy Ultra 360®	4898715-01						
Contiplex® Tuohy Ultra 360®	4898704-27						
Contiplex® Tuohy Ultra 360®	4898705-27						
Contiplex® Tuohy Ultra 360®	4898710-27						

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Contiplex® Tuohy Ultra 3600®	Article Number (under MDR application)	4898715-27					N/A
Discofix®	4099117	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix®	4095111						N/A
Discofix®	4095120						N/A
Discofix®	4095146						N/A
Discofix®	4095111IN						N/A
Discofix®	409511CN						N/A
Discofix®	409512CN						N/A
Discofix®	16466						N/A
Discofix®	4098102						N/A
Discofix®	409810CN						N/A
Discofix®	4098218						N/A
Discofix®	409821CN						N/A
Discofix®	4098501						N/A
Discofix®	4098234						N/A
Discofix®	4098080						N/A
Discofix®	4055150						N/A
Discofix®	4055145						N/A
Discofix®	4055146						N/A
Discofix®	4055149						N/A
Discofix®	4055147						N/A
Discofix®	4055148						N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix®	4099010							N/A
Discofix®	4095210		G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246584
Nutritub® ENFit® Intestinal	9246605		NB0123					9246586
Nutritub® ENFit® Intestinal	9246604		B. Braun Avitum Italy S.p.A.					9246576
								9246578
Nutritub® Gastral Basic ENFit®	9246603		G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246519
Nutritub® Gastral Basic ENFit®	9246602		NB0123					9246518
Nutritub® Gastral Basic ENFit®	9246601		B. Braun Avitum Italy S.p.A.					9246516
Nutritub® Gastral Basic ENFit®	9246600							9246550
Nutritub® Gastral Basic ENFit®	9246599							9246515
Nutritub® Gastral Basic ENFit®	9246598							9246592
Nutritub® Gastral Basic ENFit®	9246597							9246514
								9246513
								9246541
								9246543

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Nutritub® Gastral Basic ENFit®	9246596							9246512
Nutritub® Gastral Basic ENFit®	9246595							9246517
								9246525
								9246533
								9246535
Nutritub® Gastral Basic ENFit®	9246594							9246509
Nutritub® Gastral Basic ENFit®	9246593							9246511
								9246508
Infusomat® Space Line	8250832SP	403923900000086839	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8250833SP
Infusomat® Space Line	8250834SP		NB0123					8250835SP
IN-Stopper	4238010	403923900000028583L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
IN-Stopper	4238011		NB0123					N/A
Comb-Stopper	4495101	40392390000008112C	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Comb-Stopper	4495152		NB0123					N/A
Combifix Adapter	5206634	40392390000008122E	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combifix Adapter	5206642		NB0123					N/A
Original Perfusor® Line	87229910	40392390000008702U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
			NB0123					
Pleurofix® No. 1	4461002	403923900000007902V	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleurofix® No. 2	4461037		NB0123					N/A
Seldinger Introducer Needle	4206096	403923900000007442N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Seldinger Introducer Needle	4206100		NB0123					N/A
Injekt® 40 Duo	9166432C	4039239000000121823	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® 40 Duo	9166432V		NB0123					N/A
Introcath Safety® 3	4251127-01	403923900000007652W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcath Safety® 3	4251127-03		NB0123					N/A
Introcath Safety® 3	4251127-04							N/A
Introcath Safety® 3	4251127IN							N/A
Introcath Safety® 3	4251127JP							N/A
Introcath Safety® 3	4251128-01							N/A
Introcath Safety® 3	4251128-03							N/A
Introcath Safety® 3	4251128-04							N/A
Introcath Safety® 3	4251128IN							N/A
Introcath Safety® 3	4251128JP							N/A
Introcath Safety® 3	4251129-01							N/A
Introcath Safety® 3	4251129-03							N/A

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Article name	Article Number (under MDR application)						
Introcane Safety® 3	4251129-04						N/A
Introcane Safety® 3	4251129-JP						N/A
Introcane Safety® 3	4251130-01						N/A
Introcane Safety® 3	4251130-03						N/A
Introcane Safety® 3	4251130-04						N/A
Introcane Safety® 3	4251130IN						N/A
Introcane Safety® 3	4251130-JP						N/A
Introcane Safety® 3	4251131-01						N/A
Introcane Safety® 3	4251131-03						N/A
Introcane Safety® 3	4251131-04						N/A
Introcane Safety® 3	4251131-JP						N/A
Introcane Safety® 3	4251132-01						N/A
Introcane Safety® 3	4251132-03						N/A
Introcane Safety® 3	4251132-04						N/A
Introcane Safety® 3	4251132IN						N/A
Introcane Safety® 3	4251133-01						N/A
Introcane Safety® 3	4251133-03						N/A
Introcane Safety® 3	4251133-04						N/A
Introcane Safety® 3	4251134-01						N/A
Introcane Safety® 3	4251134-03						N/A
Introcane Safety® 3	4251134-04						N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)										
Introcann Safety®	4251135-01	4039239000000086737					N/A					
Introcann Safety®	4251135-03						N/A					
Introcann Safety®	4251135-04						N/A					
Introcann Safety®	4251136-01						N/A					
Introcann Safety®	4251136-03						N/A					
Introcann Safety®	4251136-04						N/A					
Introcann Safety®	4251137-01						N/A					
Introcann Safety®	4251137-03						N/A					
Introcann Safety®	4251137-04						N/A					
Introcann Safety®	4251144-01						N/A					
											N/A	
Infusomat® Space Line	8700036SP						G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line	8700435SP						NB0123					N/A
Infusomat® Space Line SafeSet	8701148SP											N/A
Infusomat® Space Line	8270066SP-01						G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8270066SP
Infusomat® Space Line	8270066SP-26	NB0123					N/A					
Infusomat® Plus Line	8700350-01	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A					
Infusomat® Plus Line	8700350-26	NB0123					N/A					
Enteroport® ENFit® Set		G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8721748					

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Schedule of Devices

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
	8721739		NB0123 B. Braun Avitum Italy S.p.A.					8721749 8721750 8721688 8721726 8721734 8721735 8721736 8721737 8721742
Enteroport® ENFI® Set	8721738							8721744 8721745 8721746 8721747
Double Spike Adaptor	4054032	40392390000007883A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Extension Line, Type: Alargadera	4094603							N/A
In-line injection tubing	4247116							N/A
LS-3 Connector	4053753	403923900000078738	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
LS-2 Connector	4097122							N/A
LS-4 Connector	4097149							N/A
LS-5 Connector	4097157							N/A
Original-Kucher-extension tubing	4887441							N/A
LS-2 Connector	9500103							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set®	8250266	40392390000007832Y	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set®	8250366							N/A
ProSet Cyto-Set®	8250370							N/A
ProSet Cyto-Set®	8250455SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250650SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250655SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250818SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250866SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250915SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250966SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250970SP							N/A
Infusomat® Space								N/A
ProSet Cyto-Set®	8250980SP							N/A
Infusomat® Space								N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto- Set® Infusomat® Space	8250991SP							N/A
ProSet Cyto- Set® Infusomat® Space	8250992SP							N/A
ProSet Cyto- Set® Infusomat® Space	8250993SP							N/A
ProSet Cyto- Set® Infusomat® Space	8250994SP							N/A
ProSet Cyto- Set® Infusomat® Space	8251055SP							N/A
ProSet Cyto- Set® Infusomat® Space	8350866SP							N/A
ProSet Cyto- Set® Infusomat® Space	8350966SP							N/A
ProSet Cyto- Set® Infusomat® Space	8351655SP							N/A
ProSet Cyto- Set® Infusomat® Space	8352055SP							N/A
ProSet Cyto- Set® Infusomat® Space	8352074SP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set® Infusomat® Space	8352075SP	403923900000078432	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set® Mix	4182700							
ProSet Cyto-Set® Mix	4182701							
ProSet Cyto-Set® Mix	4182702							
ProSet Cyto-Set® Mix	4182705							
ProSet Cyto-Set® Mix	4182706							
ProSet Cyto-Set® Mix	4182708							
ProSet Cyto-Set® Mix	4182709							
ProSet Cyto-Set® Line	4182710							
ProSet Cyto-Set® Line	4182711							
ProSet Cyto-Set® Line	4182726							
ProSet Cyto-Set® Mix	4182727							
ProSet Cyto-Set® Mix	4182728							
ProSet Cyto-Set® Line	4182729							
ProSet Cyto-Set® Mix	4182734							
ProSet Cyto-Set® Line	4182817							
ProSet Cyto-Set® Mix	4188090							
ProSet Cyto-Set® Mix	4188091							
ProSet Cyto-Set® Mix	4188092							
ProSet Cyto-Set® Line	4188093							

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
ProSet Cyto-Set® Mix	4188925						
ProSet Cyto-Set® Mix	4188926	4039239000000078534	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set® Pump Adapter	4182704						
Cyto-Set® Pump Adapter	A 1673SO	NB0123					N/A
Dosifix®	4037011	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Dosifix®	4037012						
Dosifix®	4037013	NB0123					N/A
Dosifix®	4037032						N/A
Dosifix®	4037031	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4033809	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4034589						
Heidelberger Extension Tubing	4038703	4039239000000078636					N/A
Heidelberger Extension Tubing	4055128						
Heidelberger Extension Tubing	4055136	NB0123					N/A
Heidelberger Extension Line, Type:	4097130						
Heidelberger Extension Line, Type:	4097173						N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Extension Line, Type: Heidelberg	4097190						
Extension Line, Type: Heidelberg	4097262						
Extension Line, Type: Heidelberg	4097290						
Extension Line, Type: Heidelberg	4097291						
Extension Line, Type: Heidelberg	4097300						
Extension Line, Type: Heidelberg	4097408						
Extension Line, Type: Heidelberg							
Extension Line, Type: Heidelberg							
Extension Line, Type: Heidelberg							
Introcan® Certo	4055764	40392390000007612N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan® Certo	4251300						
Introcan® Certo	4251318						
Introcan® Certo	4251326						
Introcan® Certo	4251334						
Introcan® Certo	4251342						
Introcan® Certo	4251350						
Introcan® Certo	4251369						
Introcan®	4252071B						
Introcan®	4252098B						
Introcan®	4252110B						
Introcan®	4252136B						
Introcan®	4252160B						
Introcan®	4252217B						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcant®	4252322B	403923900000007602L	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcant®-W Certo	4253302							N/A
Introcant®-W Certo	4253310							N/A
Introcant®-W Certo	4253329							N/A
Introcant®-W Certo	4253337							N/A
Introcant®-W Certo	4253345							N/A
Introcant®-W Certo	4253353							N/A
Introcant®-W Certo	4253361							N/A
Introcant®-W Certo	4254074B							N/A
Introcant®-W Certo	4254090B							N/A
Introcant®-W Certo	4254112B							N/A
Introcant®-W Certo	4254139B							N/A
Introcant®-W Certo	4254171B							N/A
Introcant®-W Certo	4254210B							N/A
Introcant®-W Certo	4254325B							N/A
Discofix® C Safeflow	16494CCN	NB0123					2028-12-31	N/A
Discofix® C Safeflow	16495CCN							N/A
Discofix® C Safeflow	16501CCN							N/A
Discofix® C Safeflow	16500CCN							N/A
Discofix® C Safeflow	16540CCN							N/A
Discofix® C Safeflow	16520CCN							N/A
Intrapur® Neonat	4099451	40392390000000802P	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrapur®	4093216		NB0123					N/A
Sterifix®	4184637							N/A

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Article name	Article Number (under MDR application)	403923900000075933	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	
Sterifix®	4099354						
Sterifix®	4099303						
Sterifix® Neonat	4099257						
Intrapur®	4099713						
Intrapur® Lipid	4099703						
Intrapur®	4183916						
Intrapur®	4099800						
Intrapur®	4099702						
Intrapur® Neonat Lipid	4099460						
Discofix® C	16500CSF-1						
Discofix® C	16540C						
Discofix® C	16494C						
Discofix® C	16801C						
Discofix® C	16494CSF						
Discofix® C	16800C						
Discofix® C	16504C						
Discofix® C	16501C						
Discofix® C	16780C						
Discofix® C	16495CSF						
Discofix® C	16613C						
Discofix® C	16609C						
Discofix® C	16503C						
Discofix® C	16605C						
Discofix® C	16751C						
Discofix® C	16502C						
Discofix® C	16612C						
Discofix® C	16740C						
Discofix® C	1651CSF						
Discofix® C	16497C						
Discofix® C	16610C						
Discofix® C	16540CSF						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix® C	16720C							N/A
Discofix® C	16520CSF							N/A
Discofix® C	16520C							N/A
Discofix® C	16701C							N/A
Discofix® C	16496C							N/A
Discofix® C	16501CSF-1							N/A
Discofix® C	RU16496C							N/A
Discofix® C	RU16495C							N/A
Discofix® C	CN16496C							N/A
Discofix® C	RU16494C							N/A
Discofix® C	EC16494C							N/A
Discofix® C	CN16494C							N/A
Discofix® C	16811C							N/A
Discofix® C	16808C							N/A
Discofix® C	16800C							N/A
Discofix® C	16501CSF							N/A
Pleuracan®	4462556	403923900000007922Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleuracan® B	4462505		NB0123					N/A
Pleuracan® Back-Check Valve	4462564	4039239000000079333	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600	5523682	40392390000000281736	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16700C	4039239000000075633	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16500C		NB0123					N/A
Discofix® C	16495C							N/A
Discofix® C	16560CSF							N/A
Discofix® C	16901C							N/A
Discofix® C	16615C							N/A

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Article name	Article Number (under MDR application)	403923900000026953G	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16560C						
Discofix® C	16494C-01						
Discofix® C	16500CSF						
Discofix® C	16551C						
Discofix® C	16500C						
Discofix® C	BR16496C						
Discofix® C	16614C	403923900000007632S	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberg Extension Tubing	4052145						
Heidelberg Extension Tubing	4052197						
Heidelberg Extension Tubing	4052197H	403923900000007632S	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety®	4251601-01						
Introcan Safety®	4251601-03						
Introcan Safety®	4251601-04						
Introcan Safety®	4251601JP						
Introcan Safety®	4251607-01						
Introcan Safety®	4251607-03						
Introcan Safety®	4251607-04						
Introcan Safety®	4251607JP						
Introcan Safety®	4251614-01						
Introcan Safety®	4251614-03	403923900000007632S	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety®	4251614-04						
Introcan Safety®	4251614JP						
Introcan Safety®	4251614JP						

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Article name	Article Number (under MDR application)						
Introcane Safety®	4251620-01						
Introcane Safety®	4251621-01						
Introcane Safety®	4251622-01						
Introcane Safety®	4251623-01						
Introcane Safety®	4251628-01						
Introcane Safety®	4251628-03						
Introcane Safety®	4251628-04						
Introcane Safety®	4251628JP						
Introcane Safety®	4251644-01						
Introcane Safety®	4251644-03						
Introcane Safety®	4251644-04						
Introcane Safety®	4251644JP						
Introcane Safety®	4251652-01						
Introcane Safety®	4251652-03						
Introcane Safety®	4251652-04						
Introcane Safety®	4251652JP						
Introcane Safety®	4251679-01						
Introcane Safety®	4251679-03						
Introcane Safety®	4251679-04						
Introcane Safety®	4251679JP						
Introcane Safety®	4251687-01						N/A

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Article name	Article Number (under MDR application)						
Introcane Safety®	4251687-03						
Introcane Safety®	4251687-04						
Introcane Safety®	4251687-JP						
Introcane Safety®	4251695-01						
Introcane Safety®	4251695-03						
Introcane Safety®	4251695-04						
Introcane Safety®	4251695-JP						
Introcane Safety®	4251709-01						
Introcane Safety®	4251709-03						
Introcane Safety®	4251709-04						
Introcane Safety®	4251709-JP						
Introcane Safety®	4251717-01						
Introcane Safety®	4251717-03						
Introcane Safety®	4251717-04						
Introcane Safety®	4251890-01						
Introcane Safety®	4251890-03						
Introcane Safety®	4251890-04						
Introcane Safety®	4252500-01						
Introcane Safety®	4252500-03						
Introcane Safety®	4252500-04						
Introcane Safety®	4252519-01						N/A

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Article name	Article Number (under MDR application)						
Introcane Safety®	4252519-03						
Introcane Safety®	4252519-04						
Introcane Safety®	4252520-01						
Introcane Safety®	4252527-01						
Introcane Safety®	4252527-03						
Introcane Safety®	4252535-01						
Introcane Safety®	4252535-03						
Introcane Safety®	4252535-04						
Introcane Safety®	4252543-01						
Introcane Safety®	4252551-01						
Introcane Safety®	4252551-03						
Introcane Safety®	4252551-04						
Introcane Safety®	4252560-01						
Introcane Safety®	4252560-03						
Introcane Safety®	4252560-04						
Introcane Safety®	4252578-01						
Introcane Safety®	4252578-03						
Introcane Safety®	4252578-04						
Introcane Safety®	4252586-01						
Introcane Safety®	4252586-04						
Introcane Safety®	4252594-01						N/A

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Article name	Article Number (under MDR application)						
Introcane Safety®	4252594-O3						N/A
Introcane Safety®	4252594-O4						N/A
Introcane Safety® W	4253523-O1						N/A
Introcane Safety® W	4253523-O3						N/A
Introcane Safety® W	4253523-O4						N/A
Introcane Safety® W	4253523-JP						N/A
Introcane Safety® W	4253540-O1						N/A
Introcane Safety® W	4253540-O3						N/A
Introcane Safety® W	4253540-O4						N/A
Introcane Safety® W	4253540-JP						N/A
Introcane Safety® W	4253566-O1						N/A
Introcane Safety® W	4253566-O3						N/A
Introcane Safety® W	4253566-O4						N/A
Introcane Safety® W	4253566-JP						N/A
Introcane Safety® W	4253574-O1						N/A
Introcane Safety® W	4253574-O3						N/A
Introcane Safety® W	4253574-O4						N/A
Introcane Safety® W	4253574-JP						N/A
Introcane Safety® W	4253590-O1						N/A
Introcane Safety® W	4253590-O3						N/A
Introcane Safety® W	4253590-O4						N/A

³ for devices with AIMDD/MDR 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)						
Introcane Safety®	4253604-01						
W							
Introcane Safety®	4253604-03						
W							
Introcane Safety®	4253604-04						
W							
Introcane Safety®	4253604-JP						
W							
Introcane Safety®	4253612-01						
W							
Introcane Safety®	4253612-03						
W							
Introcane Safety®	4253612-04						
W							
Introcane Safety®	4253639-01						
W							
Introcane Safety®	4253639-03						
W							
Introcane Safety®	4253639-JP						
W							
Introcane Safety®	4253639-04						
W							
Introcane Safety®	4254503-01						
W							
Introcane Safety®	4254503-03						
W							
Introcane Safety®	4254503-04						
W							
Introcane Safety®	4254511-01						
W							
Introcane Safety®	4254511-03						
W							
Introcane Safety®	4254511-04						
W							
Introcane Safety®	4254538-01						
W							
Introcane Safety®	4254538-03						
W							
Introcane Safety®	4254538-04						
W							
Introcane Safety®	4254546-01						
W							

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Schedule of Devices

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Article name	Article Number (under MDR application)						
Introcane Safety®	4254546-03						N/A
Introcane Safety®	4254554-01						N/A
Introcane Safety®	4254554-03						N/A
Introcane Safety®	4254554-04						N/A
Introcane Safety®	4254562-01						N/A
Introcane Safety®	4254562-03						N/A
Introcane Safety®	4254562-04						N/A
Introcane Safety®	4254570-01						N/A
Introcane Safety®	4254570-03						N/A
Introcane Safety®	4254570-04						N/A
Introcane Safety®	4254597-01						N/A
Introcane Safety®	4254597-03						N/A
Introcane Safety®	4254597-04						N/A
ProSet Intrapur®	4183913	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Intrapur®	4183925						N/A
ProSet Intrapur®	4183926						N/A
ProSet Intrapur®	4183927						N/A
ProSet Intrapur®	4183948						N/A
ProSet Intrapur®	4183949						N/A
ProSet Intrapur®	4184004						N/A
ProSet Intrapur®	4184006						N/A

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Schedule of Devices

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	
ProSet Intrapur®	4184007						
ProSet Intrapur®	4184008						
ProSet Intrapur®	4098725						
ProSet Intrapur®	4081002						
ProSet Sterifix® Naonat	4099265						
ProSet Intrapur®	4187822						
ProSet Intrapur®	4184001						
ProSet Intrapur®	4183255						
ProSet Intrapur®	4183245						
ProSet Intrapur®	4183240						
ProSet Intrapur®	4180351						
ProSet Intrapur®	4180350						
ProSet Discorfix® C	4188960						
ProSet Discorfix® C	4188959						
ProSet Discorfix® C	4188957						
ProSet Discorfix® C	4188105						
ProSet Discorfix® C	4188071						
ProSet Discorfix® C	4187954						
ProSet Discorfix® C	4187826						
ProSet Discorfix® C	4187202						

³ for devices with AIMDD/MDR 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)						
ProSet Discorfix® C	4187199						N/A
ProSet Discorfix® C	4187032						N/A
ProSet Discorfix® C	4184963						N/A
ProSet Discorfix® C	4184491						N/A
ProSet Discorfix® C	4184246						N/A
ProSet Discorfix® C	4184030						N/A
ProSet Discorfix® C	4184022						N/A
ProSet Discorfix® C	4182635						N/A
ProSet Discorfix® C	4181234						N/A
ProSet Discorfix® C	4180965						N/A
ProSet Discorfix® C	4086481						N/A
ProSet Discorfix® C	4085230						N/A
ProSet Discorfix® C	4085213						N/A
ProSet Discorfix® C	4187203						N/A
ProSet Discorfix® C	4182308						N/A
ProSet Discorfix® C	4187527						N/A
ProSet Discorfix® C	4180437						N/A
ProSet Discorfix® C	4183088						N/A
ProSet Discorfix® C	4086698						N/A
ProSet Discorfix® C	4084792						N/A
ProSet Discorfix® C	4085300SF						N/A

³ for devices with AIMDD/MDR 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)						
ProSet Discorfix® C	4085086						
ProSet Discorfix® C	4181027						
ProSet Discorfix® C	4184005						
ProSet Discorfix® C	4187291						
ProSet Discorfix® C	4183312						
ProSet Discorfix® C	4185366						
ProSet Discorfix® C	4185927						
ProSet Discorfix® C	4188188						
ProSet Discorfix® C	4086482						
ProSet Discorfix® C	4184327						
ProSet Discorfix® C	4180439						
ProSet Discorfix® C	4180306						
ProSet Discorfix® C	4182944						
ProSet Discorfix® C	4083255						
ProSet Discorfix® C	4187911						
ProSet Discorfix® C	4187623						
ProSet Discorfix® C	4187678						
ProSet Discorfix® C	4085168						
ProSet Discorfix® C	4189821						
ProSet Discorfix® C	4188958						
ProSet Discorfix® C	4187213						

³ for devices with AIMDD/MDR 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)						
ProSet Discorfix® C	4187880						N/A
ProSet Discorfix® C	4083254						N/A
ProSet Discorfix® C	4189847						N/A
ProSet Discorfix® C	4188198						N/A
ProSet Discorfix® C	4183510						N/A
ProSet Discorfix® C	4187033						N/A
ProSet Discorfix® C	4188072						N/A
ProSet Discorfix® C	4183787						N/A
ProSet Discorfix® C	4180678						N/A
ProSet Discorfix® C	4180679						N/A
ProSet Discorfix® C	4187879						N/A
ProSet Discorfix® C	4185928						N/A
ProSet Discorfix® C	4088879						N/A
ProSet Discorfix® C	4188047						N/A
ProSet Discorfix® C	4189839						N/A
ProSet Discorfix® C	4183852						N/A
ProSet Discorfix® C	4185985						N/A
ProSet Discorfix® C	4085450SF						N/A
ProSet Discorfix® C	4089464						N/A
ProSet Discorfix® C	4182737						N/A
ProSet Discorfix® C	4180300						N/A

³ for devices with AIMDD/MDR 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)						
ProSet Discorfix® C	4183777						N/A
ProSet Discorfix® C	4186972						N/A
ProSet Discorfix® C	4184521						N/A
ProSet Discorfix® C	4182652						N/A
ProSet Discorfix® C	4184483						N/A
ProSet Discorfix® C	4087930						N/A
ProSet Discorfix® C	4184817						N/A
ProSet Discorfix® C	4187391						N/A
ProSet Discorfix® C	4182720						N/A
ProSet Discorfix® C	4185821N						N/A
ProSet Discorfix® C	4085434SF						N/A
ProSet Discorfix® C	4188225						N/A
ProSet Discorfix® C	4188580						N/A
ProSet Discorfix® C	4186579						N/A
ProSet Discorfix® C	4085500SF						N/A
ProSet Discorfix® C	4181778						N/A
ProSet Discorfix® C	4180459						N/A
ProSet Discorfix® C	4188510						N/A
ProSet Discorfix® C	4180438						N/A
ProSet Discorfix® C	4086945						N/A
ProSet Discorfix® C	4187898						N/A

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Article name	Article Number (under MDR application)	G1 012974 0507 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Discorfix® C	4185021						
ProSet Discorfix® C	4187529						
ProSet Discorfix® C	4088520						
ProSet Discorfix® C	4181028						
ProSet Discorfix® C	4182638						
ProSet Discorfix® C	4088699						
ProSet Discorfix® C	4180120						
ProSet Discorfix® C	4180677						
ProSet Discorfix® C	4182633						
ProSet Discorfix® C	4182639						
ProSet Discorfix® C	4187638						
ProSet Discorfix® C	4084510						
ProSet Discorfix® C	4182651						
ProSet Discorfix® C	4187834						
ProSet Discorfix® C	4180445						
ProSet Discorfix® C	4083777						
ProSet Discorfix® C	4187308						
ProSet Discorfix® C	4184424						
ProSet Discorfix® C	4182182						
Vasorfix® Braunüle®	4268091B						N/A
Vasorfix® Braunüle®	4268113B						N/A

³ for devices with AIMDD/MDR 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)						
Vasofix® BraunUle®	4268130B						N/A
Vasofix® BraunUle®	4268156B						N/A
Vasofix® BraunUle®	4268172B						N/A
Vasofix® BraunUle®	4268210B						N/A
Vasofix® BraunUle®	4268334B						N/A
Vasofix® Certo	4269071						N/A
Vasofix® Certo	4269098						N/A
Vasofix® Certo	4269110						N/A
Vasofix® Certo	4269136						N/A
Vasofix® Certo	4269152						N/A
Vasofix® Certo	4269179						N/A
Vasofix® Certo	4269217						N/A
Vasofix® Certo	4269225						N/A
Vasofix® Certo	4269330						N/A
Extension Line	4051807	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Extension Line	4054393						N/A
Extension Line	4054394						N/A
Extension Line	4055137						N/A
Extension Line	4055138						N/A
Extension Line	4055139						N/A
Extension Line	4055140						N/A
ProSet Extension Line	4090144						N/A
ProSet Spiral Line	4090365						N/A

³ for devices with AIMDD/MDR 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)	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Spiral Line	4090373							
ProSet Spiral Line	4090381							
ProSet Spiral Line	4090383							
ProSet Spiral Line	4090390							
ProSet Spiral Line	4090438							
ProSet Extension Line	4091621							
ProSet Extension Line	4091622							
ProSet Extension Line	4091660							
Vasofix® Safety	4268091S-01	40392390000007642U	NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasofix® Safety	4268091S-03							
Vasofix® Safety	4268113S-01							
Vasofix® Safety	4268113S-03							
Vasofix® Safety	4268130S-01							
Vasofix® Safety	4268130S-03							
Vasofix® Safety	4268156S-01							
Vasofix® Safety	4268156S-03							
Vasofix® Safety	4268172S-01							
Vasofix® Safety	4268172S-03							
Vasofix® Safety	4268210S-01							
Vasofix® Safety	4268210S-03							
Vasofix® Safety	4268334S-01							

³ for devices with AIMDD/MDR 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)						
Vasofix® Safety	4268334S-03							N/A
Vasofix® Safety	4269071S-01							N/A
Vasofix® Safety	4269071S-03							N/A
Vasofix® Safety	4269071SIN							N/A
Vasofix® Safety	4269071S-20							N/A
Vasofix® Safety	4269098S-01							N/A
Vasofix® Safety	4269098S-03							N/A
Vasofix® Safety	4269098SIN							N/A
Vasofix® Safety	4269098S-20							N/A
Vasofix® Safety	4269110S-01							N/A
Vasofix® Safety	4269110S-03							N/A
Vasofix® Safety	4269110SIN							N/A
Vasofix® Safety	4269110S-20							N/A
Vasofix® Safety	4269136S-01							N/A
Vasofix® Safety	4269136S-03							N/A
Vasofix® Safety	4269136SIN							N/A
Vasofix® Safety	4269136S-20							N/A
Vasofix® Safety	4269152S-01							N/A
Vasofix® Safety	4269152S-03							N/A
Vasofix® Safety	4269152S-20							N/A
Vasofix® Safety	4269179S-01							N/A

³ for devices with AIMDD/MDR 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)						
Vasofix® Safety	4269179S-03						N/A
Vasofix® Safety	4269179SIN						N/A
Vasofix® Safety	4269179S-20						N/A
Vasofix® Safety	4269217S-01						N/A
Vasofix® Safety	4269217S-03						N/A
Vasofix® Safety	4269217S-20						N/A
Vasofix® Safety	4269225S-01						N/A
Vasofix® Safety	4269225S-03						N/A
Vasofix® Safety	4269225S-20						N/A
Vasofix® Safety	4269330S-01						N/A
Vasofix® Safety	4269330S-03						N/A
Vasofix® Safety	4269330S-20						N/A
ProSet Spiral Line	4091728	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Spiral Line	4091736						N/A
ProSet Spiral Line	4091740						N/A
ProSet Spiral Line	4091752						N/A
ProSet Spiral Line	4092539						N/A
ProSet Spiral Line	4092937						N/A
ProSet Spiral Line	4092945						N/A
ProSet Spiral Line	4092953						N/A
ProSet Spiral Line	4092961						N/A
ProSet Spiral Line							N/A

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Article name	Article Number (under MDR application)						
ProSet Spiral Line	4092970						N/A
ProSet Extension Line	4093054						N/A
ProSet Spiral Line	4093115						N/A
ProSet Spiral Line	4093130						N/A
ProSet Spiral Line	4093150						N/A
ProSet Spiral Line	4093170						N/A
ProSet Spiral Line	4093185						N/A
ProSet Spiral Line	4093215						N/A
ProSet Spiral Line	4093230						N/A
ProSet Spiral Line	4093250						N/A
ProSet Spiral Line	4093270						N/A
ProSet Spiral Line	4093285						N/A
ProSet Extension Line	4093402						N/A
ProSet Extension Line	4093437						N/A
ProSet Spiral Line	4093585						N/A
ProSet Spiral Line	4093607						N/A
ProSet Spiral Line	4093830						N/A
ProSet Spiral Line	4093850						N/A
ProSet Spiral Line	4093870						N/A
ProSet Spiral Line	4093885						N/A

³ for devices with AIMDD/MDR 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)	40392390000014782X NB0123 4039239000000259235 NB0123	G1 012974 0607 NB0123 G1 012974 0607 NB0123				
ProSet Extension Line	4095251						
ProSet Extension Line	4097531						
Extension Line	4097572						
ProSet Spiral Line	4099362						
ProSet Extension Line	4185841						
ProSet Extension Line	4185842						
ProSet Spiral Line	4187466						
ProSet Spiral Line	4187467						
ProSet Spiral Line	4187468						
ProSet Spiral Line	4187469						
ProSet Spiral Line	4188080						
Extension Line	9500049						
Extension Line	9500057						
Extension Line	9500065						
Infusomat@plus Line SafeSet	8700390			TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat@plus Line SafeSet	8700391			TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat@plus Line SafeSet	8700392			TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

³ for devices with AIMDD/MDR 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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Infusomat® Space Line SafeSet	Article Number (under MDR application)	403923900000014772V	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	8700140SP						
Infusomat® Space Line SafeSet	8700141SP	4039239000000259133	NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line SafeSet	8700142SP						
Intrafix® Primeline	4060369L	403923900000007812U	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	4060407						
	4062158						
	4062158C						
	4062182						
	4062955						
	4062957E						
	4062981L						
	4062982L						
	4062983L						
	4063000						
	4063001						
	4063003						
	4063004						
Intrafix® SafeSet	4063004C						
	4063004M						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® SafeSet	4063005	4039239000000281736	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4063006							N/A
Drainobag® Basse Pression	5524237							N/A
Drainobag® Lock 300	5523390							N/A
Drainobag® 150	5523753							N/A
Drainobag® Lock 150	5523761	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 150	55237611							N/A
Drainobag® Lock 400	5523602							N/A
Drainobag® 600 V	5523605							U2000600
Drainobag® Lock 600 V	5523648							N/A
Drainobag® Lock 600 V	5523649							N/A
Drainobag® Basse Pression TL	5524210							N/A
Drainobag® 300 V	5522322							N/A
Drainobag® Lock 300 V	5522340							N/A
Drainobag® Lock 300 V	55223401							N/A
Drainobag® 150 V	5523702							N/A
Drainobag® 150 VL	5523710							N/A
Drainobag® Lock 150 V	5523729							N/A
Drainobag® Lock 150 VL	5523737							N/A
Drainobag® Lock 150 VL	55237371							N/A

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Article name	Article Number (under MDR application)	403923900000028193A	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® 400 V	5523601						
Drainobag® Lock 400 V	5523603	NB0123	NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 K 10	5523400						
Drainobag® Lock 600 K 10	5523401						
Drainobag® Lock 600 K 12	5523427						
Drainobag® Lock 600 K 12	5523428						
Intrafix® SafeSet	4063144						
Intrafix® SafeSet	4063148	40392390000007812U	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4063287						
ProSet Intrafix® Primeline	4088549						
Intrafix® SafeSet	4110000						
Intrafix® SafeSet	4110010						
ProSet Intrafix® Primeline	4180038						
ProSet Intrafix® SafeSet	4182001A						
ProSet Intrafix® SafeSet	4182002A						
ProSet Intrafix® SafeSet	4182097						
ProSet Intrafix® SafeSet	4182098						

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Article name	Article Number (under MDR application)						
ProSet Intrafix® Primeline	4182111						
ProSet Intrafix® SafeSet	4182179						
ProSet Intrafix® SafeSet	4182409						
ProSet Intrafix® SafeSet	4183450						
ProSet Intrafix® SafeSet	4183455						
ProSet Intrafix® SafeSet	4183665						
ProSet Intrafix® Primeline	4183791						
ProSet Intrafix® SafeSet	4184321						
ProSet Intrafix® SafeSet	4186097						
ProSet Intrafix® SafeSet	4186109						
ProSet Intrafix® SafeSet	4186110						
ProSet Intrafix® Primeline	4186168						
ProSet Intrafix® Primeline	4186320						
ProSet Intrafix® Primeline	4186711						

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Article name	Article Number (under MDR application)						
ProSet Intrafix® Primeline	4186950						
ProSet Intrafix® SafeSet	4186980						
ProSet Intrafix® SafeSet	4186981						
ProSet Intrafix® Primeline	4187005						
ProSet Intrafix® SafeSet	4187006						
ProSet Intrafix® Primeline	4187007						
ProSet Intrafix® Primeline	4187008						
ProSet Intrafix® SafeSet	4187009						
ProSet Intrafix® Primeline	4187010						
ProSet Intrafix® SafeSet	4187011						
ProSet Intrafix® SafeSet	4187113						
ProSet Intrafix® Primeline	4187172						
ProSet Intrafix®	4187176						
ProSet Intrafix® Primeline	4187334						

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Article name	Article Number (under MDR application)						
ProSet Intrafix® Primeline	4187555						N/A
ProSet Intrafix® Primeline	4187946						N/A
ProSet Intrafix® SafeSet	4187989						N/A
ProSet Intrafix® Primeline	4188020						N/A
ProSet Intrafix® SafeSet	4188030						N/A
ProSet Intrafix® SafeSet	4188110						N/A
ProSet Intrafix® SafeSet	4188113						N/A
ProSet Intrafix® SafeSet	4188114						N/A
ProSet Intrafix® SafeSet	4188115						N/A
ProSet Intrafix® SafeSet	4188116						N/A
ProSet Intrafix® SafeSet	4188117						N/A
ProSet Intrafix® Primeline	4187105						N/A
ProSet Intrafix® SafeSet	4188120						N/A
ProSet Intrafix® SafeSet	4188136						N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
ProSet Intrafix® SafeSet	4188137						
ProSet Intrafix® SafeSet	4188140						
ProSet Intrafix® SafeSet	4188155						
ProSet Intrafix® SafeSet	4188159						
ProSet Intrafix® SafeSet	4188170						
ProSet Intrafix® SafeSet	4188530						
ProSet Intrafix® SafeSet	4188531						
ProSet Intrafix® SafeSet	4188540						
ProSet Intrafix® SafeSet	4188550						
ProSet Intrafix® SafeSet	4189109						
ProSet Intrafix® SafeSet	4189582						
ProSet Intrafix® SafeSet	4188119		G2S 01297/4 0457 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4062877		G1 01297/4 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4062878		NB0123				N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® Primeline	4110001							N/A
Intrafix® Primeline	4110002							N/A
ProSet Intrafix®	4186914							N/A
Intrafix® Primeline	4060563	403923900000014822N	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063000A	403923900000007822W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063001CN							N/A
SafeSet	4063003CN							N/A
SafeSet	4063004CN							N/A
SafeSet	4063004SFCN							N/A
SafeSet	4063005CN							N/A
SafeSet	4063006CN							N/A
Infusomat® Plus Line	8700340CN	403923900000008622V	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700330CN							N/A
Infusomat® Plus Line SafeSet	8700240-20							N/A
Infusomat® Plus Line SafeSet	8700280							N/A
Infusomat® Plus Line SafeSet	8700300							N/A
Infusomat® Plus Line	8700340							N/A
Infusomat® Plus Line SafeSet	8700250							N/A
Infusomat® Plus Line SafeSet	8700240							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)						
Infusomat® Plus Line SafeSet	8700220							N/A
Infusomat® Plus Line	8700330							N/A
Infusomat® Plus Line	8700320							N/A
ProSet Original Perfusor® Line	4092930	40392390000014802J	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Original Perfusor® Line	4183945		NB0123					N/A
ProSet Original Perfusor® Line	4183943							N/A
ProSet Original Perfusor® Line	4183941							N/A
ProSet Original Perfusor® Line	4183938							N/A
ProSet Original Perfusor® Line	8723017CN							N/A
Original Perfusor® Line	8722919							N/A
Original Perfusor® Line	8723017							N/A
Original Perfusor® Line	8722919-20							N/A
Original Perfusor® Line	8723017-20							N/A
Original Perfusor® Line	8723018							N/A
ProSet Original Perfusor® Line	4183968							N/A
ProSet Original Perfusor® Line	4093000							N/A
ProSet Original Perfusor® Line	4183937							N/A
ProSet Original Perfusor® Line	4183942							N/A
ProSet Original Perfusor® Line	4183947							N/A
ProSet Original Perfusor® Line	4183930							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Original Perfusion® Line	4183933	4039239000000086533	G1 012974 0607 NB0123			TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Original Perfusion® Line	4183935							
ProSet Original Perfusion® Line	4183936							
Infusomat® Plus Line	8700350CN							
Infusomat® Plus Line	8700350-20	403923900000008693B	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700360							
Infusomat® Space Line	8700192SP							
Infusomat® Space Line	8270074SP	4039239000000086635	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	8250906SP							
ProSet Infusomat® Space Line	8250902SP							
ProSet Infusomat® Space Line	8250900SP							
ProSet Infusomat® Space Line	8250077SP							
ProSet Infusomat® Space Line	4182586SP							
ProSet Infusomat® Space Line	4181557SP							
ProSet Infusomat® Space Line	8250958SP							
ProSet Infusomat® Space Line								
ProSet Infusomat® Space Line								

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³ for devices with AIMDD/MDR 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)						
Infusomat® Plus Line	8700370CN	403923900000008632X	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700400		NB0123					N/A
Infusomat® Plus Line	8700370							N/A
Omnican® fine	9167641WE	40392390000001006ZF	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican® fine	9167650WE		NB0123					N/A
Omnican® fine	9167684WE							N/A
Omnican® fine	9167820WE							N/A
Omnican® fine	929G12S-03							N/A
Omnican® fine	929G12S-41							N/A
Omnican® fine	929G12S-43							N/A
Omnican® fine	931G04S-03							N/A
Omnican® fine	931G04S-41							N/A
Omnican® fine	931G04S-43							N/A
Omnican® fine	931G04SCN							N/A
Omnican® fine	931G06S-03							N/A
Omnican® fine	931G06S-41							N/A
Omnican® fine	931G06S-43							N/A
Omnican® fine	931G06S-AP							N/A
Omnican® fine	931G06SCN							N/A
Omnican® fine	931G06SCN1							N/A
Omnican® fine	931G08S-03							N/A
Omnican® fine	931G08S-41							N/A
Omnican® fine	931G08S-43							N/A
Omnican® fine	931G08S-44							N/A
Omnican® fine	932G04S-03							N/A
Omnican® fine	932G04S-41							N/A
Omnican® fine	932G04S-43							N/A
Omnican® fine	932G04S-AP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnican® fine	932G04SCN							N/A
Omnican® fine	932G04SCN1							N/A
Omnican® fine	932G05SCN							N/A
Omnican® fine	932G05SCN1							N/A
Omnican® fine	932G06S-03							N/A
Omnican® fine	932G06S-41							N/A
Omnican® fine	932G06S-43							N/A
Omnican® fine	932G06SCN							N/A
Omnican® fine	932G06SCN1							N/A
Omnican® fine	932P04							N/A
Omnican® fine	932P05							N/A
Omnican® fine	932P06							N/A
Infusomat® Plus Line SafeSet	8700270		G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700260-20							N/A
Infusomat® Plus Line SafeSet	8700260							N/A
Original Perfusor® Line	8722865	40392390000008722Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700410	40392390000008642Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4182190SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4180639SP							N/A
ProSet Infusomat® Space Line	4180020SP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
ProSet Infusomat® Space Line	8250918SP						
ProSet Infusomat® Space Line	8251001SP						
ProSet Infusomat® Space Line	8251002SP						
ProSet Infusomat® Space Line	4182191SP						
ProSet Infusomat® Space Line	4183900						
ProSet Infusomat® Space Line	8270058SP						
ProSet Infusomat® Space Line	8252658SP						
ProSet Infusomat® Space Line	8250358SP						
ProSet Infusomat® Space Line	8250903SP						
ProSet Infusomat® Space Line	4182653SP						
ProSet Infusomat® Space Line	4187897						
ProSet Infusomat® Space Line	4184904SP						
ProSet Infusomat® Space Line	4188063SP						
ProSet Infusomat® Space Line	4180635SP						

³ for devices with AIMDD/MDR 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)					
ProSet Infusomat® Space Line	4188166SP						
ProSet Infusomat® Space Line	4189980SP						
ProSet Infusomat® Space Line	4188524SP						
ProSet Infusomat® Space Line	4189979SP						
ProSet Infusomat® Space Line	4089340SP						
ProSet Infusomat® Space Line	8250905SP						
ProSet Infusomat® Space Line	4183911						
ProSet Infusomat® Space Line	4185489						
ProSet Infusomat® Space Line	4187769SP						
ProSet Infusomat® Space Line	8251284SP						
ProSet Infusomat® Space Line	4185308SP						
ProSet Infusomat® Space Line	8250904SP						
ProSet Infusomat® Space Line	4186466SP						
ProSet Infusomat® Space Line	8700095SP						
ProSet Infusomat® Space Line	8700110SP						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Infusomat® Space Line	8270350SP						
Infusomat® Space Line	8250710SP						N/A
Infusomat® Space Line	8250731SP						N/A
Infusomat® Space Line	8700131SP						N/A
Infusomat® Space Line	8250719SP						N/A
ProSet	4183878SP						N/A
Infusomat® Space Line	4180633SP						N/A
Infusomat® Space Line	8250718SP						N/A
Infusomat® Space Line	8700098SP						N/A
Infusomat® Space Line	8701149SP						N/A
Infusomat® Space Line	8700130SP						N/A
Infusomat® Space Line	8700118SP						N/A
Infusomat® Space Line	8250720SP						N/A
ProSet	4183918						N/A
ProSet	4183910						N/A
ProSet	4187789SP						N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
ProSet Infusomat® Space Line	4186976SP						
ProSet Infusomat® Space Line	4181558SP						
ProSet Infusomat® Space Line	4089391SP						
ProSet Infusomat® Space Line	8270597SP						
Infusomat® Space Line	8270358SP						
ProSet Infusomat® Space Line	4187899						
ProSet Infusomat® Space Line	4183189SP						
ProSet Infusomat® Space Line	4186940SP						
Infusomat® Space Line	8700087SP-26						
Infusomat® Space Line	8700087SP-01						
ProSet Infusomat® Space Line	8251005SP						
ProSet Infusomat® Space Line	8251004SP						
ProSet Infusomat® Space Line	8251003SP						
ProSet Infusomat® Space Line	4183950SP						
ProSet Infusomat® Space Line	4180631SP						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
ProSet Infusomat® Space Line	41833901						
ProSet Infusomat® Space Line	4189981SP						
ProSet Infusomat® Space Line	4187377						
ProSet Infusomat® Space Line	4182189SP						
ProSet Infusomat® Space Line	8252659SP						
ProSet Original Perfusor® Line	4185687						
ProSet Original Perfusor® Line	4085129						
ProSet Original Perfusor® Line	8250803						
ProSet Original Perfusor® Line	4183971						
ProSet Original Perfusor® Line	4183970	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	
Original Perfusor® Line	8255504N						
Original Perfusor® Line	8745919N						
Original Perfusor® Line	8722940						
Original Perfusor® Line	8723060CN						
Original Perfusor® Line	8255253						
Original Perfusor® Line	8723024						
Original Perfusor® Line	8723023						
Original Perfusor® Line	8723026						
Original Perfusor® Line							

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Original Perfusor® Line	8723025						
Original Perfusor® Line	8723021						
Original Perfusor® Line	8723020						
ProSet Original Perfusor® Line	8250782						
ProSet Original Perfusor® Line	8250847						
Original Perfusor® Line	8722941						
Original Perfusor® Line	8722960						
Original Perfusor® Line	8250146						
Original Perfusor® Line	8723060						
ProSet Original Perfusor® Line	4185595						
Original Perfusor® Line	8272565						
Original Perfusor® Line	8255067						
Original Perfusor® Line	8722960-20						
Original Perfusor® Line	8255504NCN						
Original Perfusor® Line	8722862-20						
Original Perfusor® Line	8723060-20						
Original Perfusor® Line	8722862						
Original Perfusor® Line	8722935						
Original Perfusor® Line	8255172						
Original Perfusor® Line	8255059						
ProSet Original Perfusor® Line	4092933						

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Article name	Article Number (under MDR application)	403923900000014792Z NB0123	G1 012974 0607		TUV SUD Product Service GmbH (NB0123)	2028-12-31	
ProSet Original Perfusion® Line	4092932						
ProSet Original Perfusion® Line	4092931						
Original Perfusion® Line	8722935CN						
Original Perfusion® Line	8722870N						
Original Perfusion® Line	8722820						
Original Perfusion® Line	8722935-20						
Original Perfusion® Line	8255490						
ProSet Original Perfusion® Line	4183969						
Original Perfusion® Line	0066088K						
Original Perfusion® Line	0066086H						
ProSet Original Perfusion® Line	4180441						
Original Perfusion® Line	0066087J						
Original Perfusion® Line	0009483H						
ProSet Infusomat® Space Line	4186850						
ProSet Infusomat® Space Line	4186842SP						
Infusomat® Space Line SafeSet	8700128SP						
Infusomat® Space Line	8700127SP						
Infusomat® Space Line	8250437SP						
Infusomat® Space Line SafeSet	8250438SP						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	8252671SP							N/A
SangoFix®	4050192	40392390000027342Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
SangoFix®	4050192H		NB0123					N/A
SangoFix®	4050193							N/A
SangoFix®	4052013							N/A
SangoFix®	4052013H							N/A
SangoFix®	4053710							N/A
SangoFix®	4053710H							N/A
SangoFix®	4146492							N/A
SangoFix®	4034228	4039239000000039ZP	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
SangoFix® Air	4050151		NB0123					N/A
SangoFix®	4051998							N/A
SangoFix®	4051998H							N/A
SangoFix®	4052005							N/A
SangoFix®	4052005H							N/A
SangoFix®	4052218H							N/A
SangoFix® Air	4080187							N/A
SangoFix®	4100514							N/A
SangoFix®	4117301							N/A
SangoFix®	4117549							N/A
Original Penutor® Line	8723001	40392390000027242W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
IntiValve®	4094000N	40392390000008102A	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Combi-Stopper	4495209	40392390000008112C	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495101R		NB0123					N/A
SafeFlow Extension Set	4097154N	40392390000008152L	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeFlow Extension Set	4097145N		NB0123					N/A
SafeFlow Extension Set	4097154							N/A
SafeFlow	409110H	40392390000008162N	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeFlow	409100CN		NB0123					N/A
SafeFlow	409101H							N/A
SafeFlow	409100H							N/A
SafeFlow Extension Set	4097148N	40392390000002722S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Omnican® 50	9151117S	40392390000009362Z	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican® 50	9151125S		NB0123				N/A
Omnican® 100	9151133S						N/A
Omnican® 100	9151141S						N/A
Omnican® 100	9151141SC						N/A
Omnican® 20	9161619S						N/A
Omnican® 40	9161627S						N/A
Omnican® 40	9161627SC						N/A
Omnican® 40	9161635S						N/A
Omnican® F	9161502S	403923900000093937	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
IBSA FSH/LH	9161530S		NB0123				N/A
Serofine™ needle	16441MS	40392390000001007ZH	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Serofine™ needle	16443MS		NB0123				N/A
Serofine® needle	16441EMD						N/A
B. Braun Pen Needle	16441CA						N/A
Pencylcap™	P1400060						N/A
Pencylcap™	P1400061						N/A
B. Braun Pen Needle	P1400062						N/A
Pencylcap™	U1244000						N/A
Pencylcap®	U1244100						N/A
B. Braun Pen Needle	P1400062CA						N/A
B. Braun Pen needle	U1244100CA						N/A
Pen Needle B. Braun F-Pen DS	P1400075						N/A
Serofine® needle	16443EMD						N/A

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Article name	Article Number (under MDR application)	403923900000028193A NB0123	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 K 14	5523443						
Drainobag® Lock 600 K 14	5523444						
Drainobag® Lock 600 K 16	5523460						
Drainobag® Lock 600 K 16	5523461						
Drainobag® 150 K 6	5523800						
Drainobag® 150 K 6	55238001						
Drainobag® 150 K 8	5523850						
Drainobag® 150 K 8	55238501						
Omnifix® 40 Duo	9161333V	40392390000001217ZW NB0123	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 100 Duo	9161376C						
Omnifix® 100 Duo	9161376V						
Omnifix® Luer Duo	4643011C	4039239000000077633 NB0123	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Luer Duo	4643100V						
Omnifix® Luer Duo	4643102C						
Omnifix® Luer Duo	4643102V						
Omnifix® Luer Duo	4643105V						
Omnifix® Luer Duo	4643119C						
Omnifix® Luer Duo	4643119V						
Omnifix® Luer Duo	4643127C						
Omnifix® Luer Duo	4643127V						

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Article name	Article Number (under MDR application)						
Omnifix® Luer Duo	4643135C	G1 012974 0607 NB0123					N/A
Omnifix® Luer Duo	4643135V						N/A
Omnifix®-F Luer Duo	9161465V						N/A
Omnifix® Luer Duo	4643161						N/A
Omnifix® Luer Lock Solo	4617022V						N/A
Omnifix® Luer Lock Solo	4617022V-03			TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Luer Lock Solo	4617029V						N/A
Omnifix® Luer Lock Solo	4617053V						N/A
Omnifix® Luer Lock Solo	4617053V-03						N/A
Omnifix® Luer Lock Solo	4617100CA						N/A
Omnifix® Luer Lock Solo	4617100V						N/A
Omnifix® Luer Lock Solo	4617100V-03						N/A
Omnifix® Luer Lock Solo	4617207V						N/A
Omnifix® Luer Lock Solo	4617207V-03						N/A
Omnifix® Luer Lock Solo	4617304F						N/A
Omnifix® Luer Lock Solo	4617509F						N/A
Omnifix® Luer Lock Solo	4617509F-03						N/A
Omnifix® Luer Lock Solo	4617510F-06						N/A
Stericam® Safety Needle	4670002S-01						N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Sterican® Safety Needle	4670005S-01		NB0123					N/A
Sterican® Safety Needle	4670006S-01							N/A
Sterican® Safety Needle	4670006SBR							N/A
Sterican® Safety Needle	4670012S-01							N/A
Sterican® Safety Needle	4670016S-01							N/A
Sterican® Safety Needle	4670020S-01							N/A
Sterican® Safety Needle	4670022S-01							N/A
Sterican® Safety Needle	4670025S-01							N/A
Sterican® Safety Needle	4670027S-01							N/A
Sterican® Safety Needle	4670028S-01							N/A
Sterican® Safety Needle	4670030S-01							N/A
Sterican® Safety Needle	4670032S-01							N/A
Sterican® Safety Needle	4670035S-01							N/A
Sterican® Safety Needle	4670035SBR							N/A
Sterican® Safety Needle	4670040S-01							N/A
Sterican® Safety Needle	4670040SBR							N/A
Sterican® Safety Needle	4670042S-01							N/A
Sterican® Safety Needle	4670045S-01							N/A
Sterican® Safety Needle	4670045SBR							N/A
Sterican® Safety Needle	4670047S-01							N/A
Sterican® Safety Needle	4670050S-01							N/A

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Article name	Article Number (under MDR application)						
Sterican® Safety Needle	4670052S-01						N/A
Sterican® Safety Needle	4670053S-01						
Sterican® Safety Needle	4670055S-01						
Sterican® Safety Needle	4670055SBR						
Sterican®	4650018						
Sterican®	4650034	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican®	4657500						
Sterican®	4657519						
Sterican®	4657527						
Sterican®	4657543						
Sterican®	4657624						
Sterican®	4657640						
Sterican®	4657667						
Sterican®	4657675						
Sterican®	4657683						
Sterican®	4657705						
Sterican®	4657799						
Sterican®	4657853						
Sterican®	4660021						
Sterican®	4665112						
Sterican®	4665120						
Sterican®	4665317						
Sterican®	4665406						
Sterican®	4665457						
Sterican®	4665465						
Sterican®	4665503						
Sterican®	4665511						
Sterican®	4665600						
Sterican®	4665635						

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Article name	Article Number (under MDR application)	40392390000007742X	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican®	4665643						
Sterican®	4665791						
Sterican®	4667093						
Sterican®	4667123						
Sterican®	9180109						
Sterican®	9180117						
Sterican®	9186158						
Sterican®	9186166						
Sterican®	9186174						
Sterican®	9186182						
Injekt®-H Luer Duo	9166297	40392390000007752Z	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022C						
Injekt® Luer Duo	4645022UA						
Injekt® Luer Duo	4645022V						
Injekt® Luer Duo	4645057C						
Injekt® Luer Duo	4645057UA						
Injekt® Luer Duo	4645057V						
Injekt® Luer Duo	4645065C						
Injekt® Luer Duo	4645103C						
Injekt® Luer Duo	4645103UA						
Injekt® Luer Duo	4645103V						
Injekt® Luer Duo	4645200C						
Injekt® Luer Duo	4645200UA						

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)	403923900000076936					
Injekt® Luer Duo	4645200V						
Injekt® Luer Duo	4647220						
Injekt®-F Luer Duo	9166033V						N/A
Sterican® Safety Needle	4670030SBR	NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670053SBR						
Contiplex® D	4898323	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898325						
Contiplex® D	4898305						
Contiplex® D	4898308						
Contiplex® D	4898311						
Contiplex® D	4898335						
Contiplex® D	4898305NR						
NRFit®	4898335NR						
NRFit®	4898311NR						
Contiplex® D	4898323NR						
Contiplex® D	4898325NR						
Contiplex® D	4895819NCN						
Contiplex® D	4894235NCN	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4894391NCN						
Contiplex® D	4898205						
Contiplex® D	4898211	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898235						
Contiplex® C	4898115	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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)						
Contiplex® C	4898130	NB0123	NB0123					N/A
Contiplex® C	4898115NR							N/A
Contiplex® C	4898130NR							N/A
Ultraplex® 360	4892603-01	40392390000008552Y	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Ultraplex® 360	4892603CN							N/A
Ultraplex® 360	4892603NR-01							N/A
NRF1®	4892603NR-01							N/A
Ultraplex® 360	4892605-01							N/A
Ultraplex® 360	4892605CN							N/A
Ultraplex® 360	4892605NR-01							N/A
Ultraplex® 360	4892608-01							N/A
Ultraplex® 360	4892608CN							N/A
Ultraplex® 360	4892608NR-01							N/A
Ultraplex® 360	4892610-01							N/A
Ultraplex® 360	4892610CN							N/A
Ultraplex® 360	4892610NR-01							N/A
NRF1®	4892615-01							N/A
Ultraplex® 360	4892615CN							N/A
Ultraplex® 360	4892615NR-01	40392390000008502N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® D	4892105							N/A
Stimuplex® D	4892105-23							N/A
Stimuplex® D	4892105CN							N/A
Stimuplex® D	4892105NR							N/A
NRF1®	4892105NR							N/A
Stimuplex® D	4892108	NB0123	NB0123					N/A
Stimuplex® D	4892108-23							N/A
Stimuplex® D	4892108CN							N/A

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Schedule of Devices

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Stimuplex® D NRFit®	4892108NR						
Stimuplex® D	4892112						N/A
Stimuplex® D	4892112-23						N/A
Stimuplex® D	4892112CN						N/A
Stimuplex® D NRFit®	4892112NR						N/A
Stimuplex® D	4892115						N/A
Stimuplex® D	4892115-23						N/A
Stimuplex® D NRFit®	4892115NR						N/A
Stimuplex® D	4892134						N/A
Stimuplex® D	4892134-23						N/A
Stimuplex® D NRFit®	4892134NR						N/A
Stimuplex® D	4892137						N/A
Stimuplex® D	4892137-23						N/A
Stimuplex® D NRFit®	4892137NR						N/A
Stimuplex® D	4892153						N/A
Stimuplex® D	4892153-23						N/A
Stimuplex® D NRFit®	4892153NR						N/A
Stimuplex® D	4892155						N/A
Stimuplex® D	4892155-23						N/A
Stimuplex® D NRFit®	4892155NR						N/A
Stimuplex® D	4892205						N/A
Stimuplex® D	4892205-23						N/A
Stimuplex® D NRFit®	4892205NR						N/A
Stimuplex® D	4892208						N/A
Stimuplex® D	4892208-23						N/A
Stimuplex® D NRFit®	4892208NR						N/A
Stimuplex® Ultra 360®	4892503-01	40392390000008512Q	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

³ for devices with AIMDD/MDR 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)	NB0123				
Stimuplex® Ultra 3600	4892503-03						
Stimuplex® Ultra 3600	4892503-04						N/A
Stimuplex® Ultra 3600	4892503-20						N/A
Stimuplex® 3600	4892503CN						N/A
Stimuplex® Ultra 3600	4892503NR-01						N/A
Stimuplex® Ultra 3600	4892505-01						N/A
Stimuplex® Ultra 3600	4892505-03						N/A
Stimuplex® Ultra 3600	4892505-04						N/A
Stimuplex® Ultra 3600	4892505-20						N/A
Stimuplex® 3600	4892505CN						N/A
Stimuplex® Ultra 3600	4892505NR-01						N/A
Stimuplex® Ultra 3600	4892508-01						N/A
Stimuplex® Ultra 3600	4892508-03						N/A
Stimuplex® Ultra 3600	4892508-04						N/A
Stimuplex® Ultra 3600	4892508-20						N/A
Stimuplex® 3600	4892508CN						N/A
Stimuplex® Ultra 3600	4892508NR-01						N/A
Stimuplex® Ultra 3600	4892510-01						N/A
Stimuplex® Ultra 3600	4892510-03						N/A
Stimuplex® Ultra 3600	4892510-04						N/A

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Article name	Article Number (under MDR application)	4039239000000044ZG					N/A
Stimuplex® Ultra 3600®	4892510-20						
Stimuplex® 3600®	4892510CN						
Stimuplex® Ultra 3600® NRFit®	4892510NR-01						
Stimuplex® Ultra 3600®	4892515-01						
Stimuplex® Ultra 3600®	4892515-03						
Stimuplex® Ultra 3600®	4892515-04						
Stimuplex® Ultra 3600®	4892515-20						
Stimuplex® 3600®	4892515CN						
Stimuplex® Ultra 3600® NRFit®	4892515NR-01						
Omnifix® Lock	4617003						
Omnifix® Lock	4617014						
Omnifix® Lock	4617021						
Omnifix® Lock	4617508F-01						
Original Perfusor® Syringe 20 ml	8728615						
Original Perfusor® Syringe 20 ml	8728615C						
Original Perfusor® Syringe 20 ml	8728623	40392390000029923R	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728623C						
Original Perfusor® Syringe 20 ml	8728810F-04						
Original Perfusor® Syringe 50 ml							

³ for devices with AIMDD/MDR 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)						
Original Perfusor® Syringe 50 ml	8728810F-06	403923900000077939	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8728810F
Original Perfusor® Syringe 50 ml	8728810F-20							N/A
Original Perfusor® Syringe 50 ml	8728844F-04							N/A
Original Perfusor® Syringe 50 ml	8728844F-06	403923900000029923R	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8728844F
Original Perfusor® Syringe 50 ml	8728844F-20							N/A
Original Perfusor® Syringe 50 ml	8728852F-04							N/A
Original Perfusor® Syringe 50 ml	8728852F-06	4039239000000207124	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728852F-20							N/A
Original Perfusor® Syringe 50 ml	8728861F-04							N/A
Original Perfusor® Syringe 50 ml	8728861F-06	40392390000000802S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728861F-20							N/A
Original Perfusor® Syringe 50 ml	8728845F-01							N/A
Cystofix®	4450100	40392390000008993R	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450120							N/A
Cystofix®	4450130							N/A

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Article name	Article Number (under MDR application)	4039239000001002Z3					
Cystofix®	4450150						
Cystofix®	4450160						
Cystofix®	4450170						
Cystofix®	4450180	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450200						
Cystofix®	4450220						
Cystofix SG	4450410						
Cystofix SG	4450412	G1 022239 0080 NB0123 B.BRAUN MEDICAL SAS	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix SG	4450414						
Cystofix SG	4450416						
Cystofix	4450010						
Cystofix	4450012	G1 022239 0080 NB0123 B.BRAUN MEDICAL SAS	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450014						
Cystofix	4450016						
Cystofix	4450512						
Cystofix	4450514	40392390000009272Y					N/A
Cystofix	4450516						
Cystofix	4450712						
Cystofix	4450714						
Cystofix	4450716	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450718						
Cystofix	4450720						
Vasco® OP Powdered	6031510						
Vasco® OP Powdered	6031525	40392390000009272Y					N/A
Vasco® OP Powdered	6031532						

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Article name	Article Number (under MDR application)						
Vasco® OP Powdered	6031546						
Vasco® OP Powdered	6031553						
Vasco® OP Powdered	6031564						
Vasco® OP Sensitive	6080990						
Vasco® OP Sensitive	6081002						
Vasco® OP Sensitive	6081010						
Vasco® OP Sensitive	6081029						
Vasco® OP Sensitive	6081037						
Vasco® OP Sensitive	6081045						
Vasco® OP Sensitive	6081053						
Vasco® OP Sensitive	6081060						
Vasco® OP Sensitive	6081199						
Vasco® OP Underglove	6081200						
Vasco® OP Underglove	6081218						
Vasco® OP Underglove	6081226						
Vasco® OP Underglove	6081234						
Vasco® OP Underglove	6081242						
Vasco® OP Underglove	6081259						
Vasco® OP Underglove	6081267						
Vasco® OP eco	6081308						
Vasco® OP eco	6081316						

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Article name	Article Number (under MDR application)						
Vasco® OP eco	6081324						
Vasco® OP eco	6081332						
Vasco® OP eco	6081340						
Vasco® OP eco	6081359						
Vasco® OP eco	6081367						
Vasco® OP eco	6081375						
Vasco® OP Grip	6081409						
Vasco® OP Grip	6081417						
Vasco® OP Grip	6081425						
Vasco® OP Grip	6081433						
Vasco® OP Grip	6081441						
Vasco® OP Grip	6081450						
Vasco® OP Grip	6081468						
Vasco® OP Grip	6081476						
Vasco® OP	9208291						
Free							
Vasco® OP	9208305						
Free							
Vasco® OP	9208313						
Free							
Vasco® OP	9208321						
Free							
Vasco® OP	9208330						
Free							
Vasco® OP	9208348						
Free							
Vasco® OP	9208356						
Free							

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasco® OP Free	9208364		G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Connection Tube Bayonet	5524913	40392390000008052H	NB0123					U2170701
Filter Needle	415040	4039239000000290000	G2S 012974 0457	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	4550404
Filter Hub	418021		NB0123					4551001
Filter Straw	415020							4550200
Filter Straw	415021							4550250
Sterifix® Filter Straw 4"	339171							4550200N
Sterifix® Filter Straw 1,75"	339170							4550250N
Sterifix® Filter Needle 1,5"	339169							4550404N

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Effective

Document History

Version	Description of Change
1.0	Initial version

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 -
Title: BBWAG_LM_confirmation letter_Regulation EU 2023/607_G10

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Title: BBWAG_LM_confirmation letter_Regulation EU 2023/607_G10

UserName: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: Wednesday, 15 May 2024, 15:10 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Wednesday, 15 May 2024, 15:24 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 15 May 2024, 16:49 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: Wednesday, 15 May 2024, 17:22 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Arico, Mareike (sommrde)
Title: HC-QM - Head of QM active MD/ Head of Regulatory Affairs CoE AIS
Date: Wednesday, 15 May 2024, 21:34 W. Europe Daylight Time
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Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10 Initiator: Anja Mai

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B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16
Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10

UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
Date: Thursday, 16 May 2024, 07:36 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Thursday, 16 May 2024, 08:19 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: Thursday, 16 May 2024, 09:09 W. Europe Daylight Time
Meaning: Final Release of the Document
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