

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:

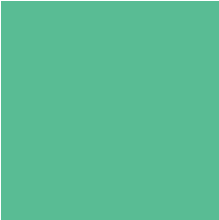
- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ 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	

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)	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Perfusor® compactplus	8717030	40392390000000038ZM					
Infusomat® compactplus	8717050	40392390000005352B	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
OnlineSuite	876100	40392390000005552H	G1 012974 0607 NB0123	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	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	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus P	8717070	403923900000007492Y	G1 012974 0607 NB0123	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	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	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	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	931M08SE		G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® 600 V	5523606	403923900000007973B					

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)						
Drug Library Manager Spaceplus	876203	403923900000169539	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drug Library Manager Spaceplus	876209	403923900000169539	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FR29914	403923900000249638	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FREU914		NB0123				N/A
GLYCINE 1,5 % B. BRAUN	FREU934						N/A
GLYCINE 1,5 % B. BRAUN	FREU954						N/A
GLYCINE 1,5 % B. BRAUN	FREU974						N/A
NaCl 0.9 % B. BRAUN	FREU850	403923900000250128	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	FREU910		NB0123				N/A
NaCl 0.9 % B. BRAUN	FREU930						N/A
NaCl 0.9 % B. BRAUN	FREU950						N/A
NaCl 0.9 % B. BRAUN	FREU970						N/A
NaCl 0.9 % B. BRAUN	3570100	40392390000026312N	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	3637006		NB0123				N/A
NaCl 0.9 % B. BRAUN	0069414E						N/A
NaCl 0.9 % B. BRAUN	3521360						N/A
NaCl 0.9 % B. BRAUN	3570120						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)	40392390000025022A G1 012974 0607 NB0123	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	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						N/A
NaCl 0.9 % B. BRAUN	3570470	NB0123	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0.9 % B. BRAUN	3570480						N/A
NaCl 0.9 % B. BRAUN	3570480						N/A
RINGER B. BRAUN	FREU984	NB0123	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	FREU924						FREU920
RINGER B. BRAUN	FREU944						N/A
RINGER B. BRAUN	FREU964						N/A
RINGER B. BRAUN	FREU984						N/A
RINGER B. BRAUN	3570000	NB0123	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	3570010						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)	40392390000026322Q	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	3570060						
RINGER B. BRAUN	3570611						
RINGER B. BRAUN	3570610						
RINGER B. BRAUN	3570614						
RINGER B. BRAUN	3570612	40392390000026332S	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570530
RINGER B. BRAUN	3570613						
Aqua B. Braun	FREU812	40392390000024973A	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	FREU852						
Aqua B. Braun	FREU912						
Aqua B. Braun	FREU932						
Aqua B. Braun	387872	40392390000026272X	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	387873						

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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	40392390000000238732	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	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							
Aqua B. Braun	0082479E	40392390000000738732	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
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							

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)	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® Space P	8713070						
Perfusor® Space	8713030	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Enteroport® plus	8710355						
Infusomat® Plus Line SafeSet	8700200	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	8700200+20						
Infusomat® Plus Line SafeSet	8700210	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	8700310						
Infusomat® Plus Line	8700310+20	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	8700310CN						
Cyto-Set® Infusomat® Space	8250414SP	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® Infusomat® Space	8250817SP						
Cyto-Set® Infusomat® Space	8250820SP	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® Infusomat® Space	8250917SP						
Cyto-Set® Infusomat® Space	8250920SP	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® 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)	Basic UDI-DI (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	403923900000078432	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Line	A2582NF						

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Cyto-Set® Mix	A2900N						
Cyto-Set® Mix	A2903N						
Cyto-Set® Mix	A2906N						
Cyto-Set® Mix	A2907N						
Cyto-Set® Mix	A2908N						
Stimuplex® A	4894251						
Stimuplex® A	4894539						
Stimuplex® A	4894367						
Stimuplex® A	4894502						
Stimuplex® A	4894375						
Stimuplex® A	4894260						
Stimuplex® A	4894278						
Stimuplex® A	4894278NR						
Stimuplex® A	4894375NR						
Stimuplex® A	4894260NR						
Stimuplex® A	4894367NR	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	
Stimuplex® A	4894539NR						
Stimuplex® A	4894502NR						
Easypump® II LT 60-12	4540002						
Easypump® II LT 60-12	4540002-07						
Easypump® II LT 60-12	4540002-20						
Easypump® II LT 500-12.5	4540003						
Easypump® II LT 500-12.5	4540003-07						
Easypump® II LT 500-12.5	4540003-20						
Easypump® II LT 80-16	4540004						

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)					
Easypump® II LT 80-16	4540004-07						
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)	Basic UDI-DI (under MDR application)					
Easypump® II LT 270-54	4540018-07						N/A
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							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							N/A
Easypump® II LT 270-68	4540026-20						N/A
Easypump® II LT 400-100	4540028						N/A
Easypump® II LT 400-100							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							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							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							N/A
Easypump® II ST 250-0.5	4540042-07						N/A
Easypump® II ST 250-0.5							N/A
Easypump® II ST 50-1	4540044						N/A

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Easyump® II ST 50-1	4540044-07						N/A
Easyump® II ST 50-1	4540044-20						N/A
Easyump® II ST 100-1	4540046						N/A
Easyump® II ST 100-1	4540046-07						N/A
Easyump® II ST 100-1	4540046-20						N/A
Easyump® II ST 250-1	4540048						N/A
Easyump® II ST 250-1	4540048-07						N/A
Easyump® II ST 250-1	4540048-20						N/A
Easyump® II ST 250-1.5	4540050						N/A
Easyump® II ST 250-1.5	4540050-07						N/A
Easyump® II ST 250-1.5	4540050-20						N/A
Easyump® II ST 400-2	4540052						N/A
Easyump® II ST 400-2	4540052-07						N/A
Easyump® II ST 400-2	4540052-20						N/A
Easyump® II ST 500-2	4540054						N/A
Easyump® II ST 500-2	4540054-07						N/A
Easyump® II ST 500-2	4540054-20						N/A
Easyump® II ST 100-2	4540056						N/A
Easyump® 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
Easypump® II ST 100-2	4540056-20						
Easypump® II ST 400-4	4540058						
Easypump® II ST 400-4	4540058-07						
Easypump® 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						
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	N/A
Contiplex® S Ultra 360® NRE1®	4898650NR-27						
Contiplex® S Ultra 360® NRE1®	4898610NR-27						
Contiplex® S Ultra 360® NRE1®	4898615NR-27						
Contiplex® Tuohy Ultra 360® NREFit®	4898704NR-01						
Contiplex® Tuohy Ultra 360® NREFit®	4898705NR-01						
Contiplex® Tuohy Ultra 360® NREFit®	4898710NR-01						
Contiplex® Tuohy Ultra 360® NREFit®	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						

Approval confirms:Correct document attached / complete document attached / scan is readable
Freigabe bestätigt: Dokument Richtig zugeordnet / vollständig und lesbar
Print Date - Gedruckt am: 2024-05-17 15:01 (CET)

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Contiplex® Tuohy Ultra 3600®	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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Discofix®	4099010						N/A
	4095210						15809
Nutritub® ENFit® Intestinal	9246605	40392390000029463J	G1 019717 0032	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246584
			NB0123				9246586
Nutritub® ENFit® Intestinal	9246604		B. Braun Avitum Italy S.p.A.				9246576
							9246578
Nutritub® Gastral Basic ENFit®	9246603	40392390000008172Q	G1 019717 0032	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
								9246517
Nutritub® Gastral Basic ENFit®	9246595							9246525
								9246533
Nutritub® Gastral Basic ENFit®	9246594							9246535
								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
Combi-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
Combi-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	87239910	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)						
		NB0123					
Pleurofix® No. 1	4461002	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	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	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	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	4251127N						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	4251128-01						N/A
Introcath Safety® 3	4251128-03						N/A
Introcath Safety® 3	4251128-04						N/A
Introcath Safety® 3	4251128-03						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)	403923900000086737	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcane Safety®	4251135-01						
Introcane Safety®	4251135-03						
Introcane Safety®	4251135-04						
Introcane Safety®	4251136-01						
Introcane Safety®	4251136-03						
Introcane Safety®	4251136-04						
Introcane Safety®	4251137-01						
Introcane Safety®	4251137-03						
Introcane Safety®	4251137-04						
Introcane Safety®	4251144-01						
Infusomat® Space Line	8700036SP						
Infusomat® Space Line	8700435SP						
Infusomat® Space Line	8701148SP						
Infusomat® SafeSet							
Infusomat® Space Line	8270066SP-01	403923900000086635	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8270066SP
Infusomat® Space Line	8270066SP-26						
Infusomat® Plus Line	8700350-01						
Infusomat® Plus Line	8700350-26						
Enteroport® ENFit® Set							
		4039239000000263732	G1 019717 0032	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8721748

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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 8721744 8721745 8721746 8721747
Enteroport® ENFI® Set	8721738							
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: Alagadera	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

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)	40392390000007832Y NB0123	G1 012974 0607	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set®	8250266						
ProSet Cyto-Set®	8250366						
ProSet Cyto-Set®	8250370						
ProSet Cyto-Set®	8250455SP						
Infusomat® Space							
ProSet Cyto-Set®	8250650SP						
Infusomat® Space							
ProSet Cyto-Set®	8250655SP						
Infusomat® Space							
ProSet Cyto-Set®	8250818SP						
Infusomat® Space							
ProSet Cyto-Set®	8250866SP						
Infusomat® Space							
ProSet Cyto-Set®	8250915SP						
Infusomat® Space							
ProSet Cyto-Set®	8250966SP						
Infusomat® Space							
ProSet Cyto-Set®	8250970SP						
Infusomat® Space							
ProSet Cyto-Set®	8250980SP						
Infusomat® Space							

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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
ProSet Cyto- Set® Infusomat® Space							N/A
ProSet Cyto- Set® Infusomat® Space							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)						
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							N/A
ProSet Cyto-Set® Mix	4182702							N/A
ProSet Cyto-Set® Mix	4182705							N/A
ProSet Cyto-Set® Mix	4182706							N/A
ProSet Cyto-Set® Mix	4182708							N/A
ProSet Cyto-Set® Line	4182709							N/A
ProSet Cyto-Set® Line	4182710							N/A
ProSet Cyto-Set® Line	4182711							N/A
ProSet Cyto-Set® Mix	4182726							N/A
ProSet Cyto-Set® Mix	4182727							N/A
ProSet Cyto-Set® Line	4182728							N/A
ProSet Cyto-Set® Mix	4182729							N/A
ProSet Cyto-Set® Line	4182734							N/A
ProSet Cyto-Set® Mix	4182817							N/A
ProSet Cyto-Set® Mix	4188090							N/A
ProSet Cyto-Set® Mix	4188091							N/A
ProSet Cyto-Set® Mix	4188092							N/A
ProSet Cyto-Set® Line	4188093							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)					
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	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 Line, Type:	4097130						
Heidelberger Extension Line, Type:	4097173	NB0123					N/A
Heidelberger							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)	40392390000007612N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
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						
Introcan® Certo	4055764						
Introcan® Certo	4251300						
Introcan® Certo	4251318						
Introcan® Certo	4251326						N/A
Introcan® Certo	4251334						
Introcan® Certo	4251342						
Introcan® Certo	4251350						
Introcan® Certo	4251369						
Introcan®	4252071B						
Introcan®	4252098B						
Introcan®	4252110B						
Introcan®	4252136B						
Introcan®	4252160B						N/A
Introcan®	4252217B						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Introcant®	4252322B	403923900000007602L	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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	4254074B						N/A
Introcant®-W	4254090B						N/A
Introcant®-W	4254112B						N/A
Introcant®-W	4254139B						N/A
Introcant®-W	4254171B						N/A
Introcant®-W	4254210B						N/A
Introcant®-W	4254325B						N/A
Discofix® C Safeflow	16494CCN	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 Safeflow	16495CCN	NB0123					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	4089451	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD 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						

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)						
Discofix® C	16720C						
Discofix® C	16520CSF						N/A
Discofix® C	16520C						N/A
Discofix® C	16701C						N/A
Discofix® C	16498C						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	16611C						N/A
Discofix® C	16608C						N/A
Discofix® C	16600C						N/A
Discofix® C	16501CSF						N/A
Pleuracan®	4462556	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	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	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	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

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)	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						
Heidelberg Extension Tubing	4052145	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	4052197						
Heidelberg Extension Tubing	4052197H						
Introcan Safety®	4251601-01	403923900000007632S	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety®	4251601-03						
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						
Introcan Safety®	4251614-04						
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

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)					
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						

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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

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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)					
Introcen Safety®	4253604-01						
Introcen Safety®	4253604-03						
Introcen Safety®	4253604-04						
Introcen Safety®	4253604-JP						
Introcen Safety®	4253612-01						
Introcen Safety®	4253612-03						
Introcen Safety®	4253612-04						
Introcen Safety®	4253639-01						
Introcen Safety®	4253639-03						
Introcen Safety®	4253639-JP						
Introcen Safety®	4253639-04						
Introcen Safety®	4254503-01						
Introcen Safety®	4254503-03						
Introcen Safety®	4254503-04						
Introcen Safety®	4254511-01						
Introcen Safety®	4254511-03						
Introcen Safety®	4254511-04						
Introcen Safety®	4254538-01						
Introcen Safety®	4254538-03						
Introcen Safety®	4254538-04						
Introcen Safety®	4254546-01						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)

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)						
Introcan Safety®	4254546-03	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety®	4254554-01						N/A
Introcan Safety®	4254554-03						N/A
Introcan Safety®	4254554-04						N/A
Introcan Safety®	4254562-01						N/A
Introcan Safety®	4254562-03						N/A
Introcan Safety®	4254562-04						N/A
Introcan Safety®	4254570-01						N/A
Introcan Safety®	4254570-03						N/A
Introcan Safety®	4254570-04						N/A
Introcan Safety®	4254597-01						N/A
Introcan Safety®	4254597-03						N/A
Introcan Safety®	4254597-04						N/A
ProSet Intrapun®	4183913						N/A
ProSet Intrapun®	4183925						N/A
ProSet Intrapun®	4183926						N/A
ProSet Intrapun®	4183927						N/A
ProSet Intrapun®	4183948						N/A
ProSet Intrapun®	4183949						N/A
ProSet Intrapun®	4184004						N/A
ProSet Intrapun®	4184006						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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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)					
ProSet Intrapur®	4184007						N/A
ProSet Intrapur®	4184008						N/A
ProSet Intrapur®	4098725						N/A
ProSet Intrapur®	4081002						N/A
ProSet Sterifix® Neonat	4099265						N/A
ProSet Intrapur®	4187822						N/A
ProSet Intrapur®	4184001						N/A
ProSet Intrapur®	4183255						N/A
ProSet Intrapur®	4183245						N/A
ProSet Intrapur®	4183240						N/A
ProSet Intrapur®	4180351						N/A
ProSet Intrapur®	4180350						N/A
ProSet Discofix® C	4188960						N/A
ProSet Discofix® C	4188959						N/A
ProSet Discofix® C	4188957						N/A
ProSet Discofix® C	4188105						N/A
ProSet Discofix® C	4188071						N/A
ProSet Discofix® C	4187954						N/A
ProSet Discofix® C	4187826						N/A
ProSet Discofix® C	4187202						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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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)					
ProSet Discofix® C	4187199						N/A
ProSet Discofix® C	4187032						N/A
ProSet Discofix® C	4184963						N/A
ProSet Discofix® C	4184491						N/A
ProSet Discofix® C	4184246						N/A
ProSet Discofix® C	4184030						N/A
ProSet Discofix® C	4184022						N/A
ProSet Discofix® C	4182635						N/A
ProSet Discofix® C	4181234						N/A
ProSet Discofix® C	4180965						N/A
ProSet Discofix® C	4086481						N/A
ProSet Discofix® C	4085230						N/A
ProSet Discofix® C	4085213						N/A
ProSet Discofix® C	4187203						N/A
ProSet Discofix® C	4182308						N/A
ProSet Discofix® C	4187527						N/A
ProSet Discofix® C	4180437						N/A
ProSet Discofix® C	4183088						N/A
ProSet Discofix® C	4086698						N/A
ProSet Discofix® C	4084792						N/A
ProSet Discofix® 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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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 Discofix® C	4085086						
ProSet Discofix® C	4181027						
ProSet Discofix® C	4184005						
ProSet Discofix® C	4187291						
ProSet Discofix® C	4183312						
ProSet Discofix® C	4185366						
ProSet Discofix® C	4185927						
ProSet Discofix® C	4188188						
ProSet Discofix® C	4086482						
ProSet Discofix® C	4184327						
ProSet Discofix® C	4180439						
ProSet Discofix® C	4180306						
ProSet Discofix® C	4182944						
ProSet Discofix® C	4083255						
ProSet Discofix® C	4187911						
ProSet Discofix® C	4187623						
ProSet Discofix® C	4187676						
ProSet Discofix® C	4085168						
ProSet Discofix® C	4189821						
ProSet Discofix® C	4188958						
ProSet Discofix® 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)

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	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	4086879						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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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	4183777						N/A
ProSet Discorfix® C	4185972						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

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 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)	G1012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Discofix® C	4185021						
ProSet Discofix® C	4187529						
ProSet Discofix® C	4088520						
ProSet Discofix® C	4181028						
ProSet Discofix® C	4182638						
ProSet Discofix® C	4088699						
ProSet Discofix® C	4180120						
ProSet Discofix® C	4180677						
ProSet Discofix® C	4182633						
ProSet Discofix® C	4182639						
ProSet Discofix® C	4187638						
ProSet Discofix® C	4084510						
ProSet Discofix® C	4182651						
ProSet Discofix® C	4187834						
ProSet Discofix® C	4180445						
ProSet Discofix® C	4083777						
ProSet Discofix® C	4187308						
ProSet Discofix® C	4184424						
ProSet Discofix® C	4182182						
Vasofix® Braunüle®	4268091B						N/A
Vasofix® 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)

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)	40392390000007893C	G1 012974 0607 NB0123				
Vasofix® Braunüle®	4268130B						
Vasofix® Braunüle®	4268156B						N/A
Vasofix® Braunüle®	4268172B						N/A
Vasofix® Braunüle®	4268210B						N/A
Vasofix® Braunüle®	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	NB0123	NB0123	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
							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)	Basic UDI-DI (under MDR application)	G1 012974 0607 NB0123		TUV SUD Product Service GmbH (NB0123)	2028-12-31	
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					
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)

Schedule of Devices

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Article name	Article Number (under MDR application)						
Vasofix® Safety	4268334S-03						
Vasofix® Safety	4269071S-01						
Vasofix® Safety	4269071S-03						
Vasofix® Safety	4269071SIN						
Vasofix® Safety	4269071S-20						
Vasofix® Safety	4269098S-01						
Vasofix® Safety	4269098S-03						
Vasofix® Safety	4269098SIN						
Vasofix® Safety	4269098S-20						
Vasofix® Safety	4269110S-01						
Vasofix® Safety	4269110S-03						
Vasofix® Safety	4269110SIN						
Vasofix® Safety	4269110S-20						
Vasofix® Safety	4269136S-01						
Vasofix® Safety	4269136S-03						
Vasofix® Safety	4269136SIN						
Vasofix® Safety	4269136S-20						
Vasofix® Safety	4269152S-01						
Vasofix® Safety	4269152S-03						
Vasofix® Safety	4269152S-20						
Vasofix® Safety	4269179S-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)

Schedule of Devices

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Article name	Article Number (under MDR application)	40392390000007893C	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)		N/A
Vasofix® Safety	4269179S-03						
Vasofix® Safety	4269179SIN						
Vasofix® Safety	4269179S-20						
Vasofix® Safety	4269217S-01						
Vasofix® Safety	4269217S-03						
Vasofix® Safety	4269217S-20						
Vasofix® Safety	4269225S-01						
Vasofix® Safety	4269225S-03						
Vasofix® Safety	4269225S-20						
Vasofix® Safety	4269330S-01						
Vasofix® Safety	4269330S-03						
Vasofix® Safety	4269330S-20						
ProSet Spiral Line	4091728					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

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)	Basic UDI-DI (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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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)	40392390000014782X 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/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Infusomat® Space Line SafeSet	Article Number (under MDR application)	403923900000014772V	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	8700140SP						
Infusomat® Space Line SafeSet	Article Number (under MDR application)	4039239000000259133	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	8700142SP						
Intrafix® Primeline	Article Number (under MDR application)	4060369L	G1 012974 0607 NB0123	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	Article Number (under MDR application)	4063004C	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	4063004M						

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Intrafix® SafeSet	4063005						
Intrafix® SafeSet	4063006	4039239000000281736	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A N/A N/A N/A N/A N/A N/A N/A N/A U2000600
Drainobag® Basse Pression	5524237						
Drainobag® Lock 300	5523390						
Drainobag® 150	5523753						
Drainobag® Lock 150	5523761						
Drainobag® Lock 150	55237611						
Drainobag® Lock 400	5523602						
Drainobag® 600 V	5523605						
Drainobag® Lock 600 V	5523648						
Drainobag® Lock 600 V	5523649						
Drainobag® Basse Pression TL	5524210	403923900000007973B	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A
Drainobag® 300 V	5522322						
Drainobag® Lock 300 V	5522340						
Drainobag® Lock 300 V	55223401						
Drainobag® 150 V	5523702						
Drainobag® 150 VL	5523710						
Drainobag® Lock 150 V	5523729						
Drainobag® Lock 150 VL	5523737						
Drainobag® Lock 150 VL	55237371						

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Drainobag® 400 V	5523601	403923900000028193A	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	U2000500
Drainobag® Lock 400 V	5523603						U2000700
Drainobag® Lock 600 K 10	5523400						N/A
Drainobag® Lock 600 K 10	5523401						N/A
Drainobag® Lock 600 K 12	5523427						N/A
Drainobag® Lock 600 K 12	5523428						N/A
Intrafix® SafeSet	4063144	40392390000007812U	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4063148						N/A
Intrafix® Primeline	4063287						N/A
ProSet Intrafix® Primeline	4088549						N/A
Intrafix® SafeSet	4110000						N/A
Intrafix® SafeSet	4110010						N/A
ProSet Intrafix® Primeline	4180038						N/A
ProSet Intrafix® SafeSet	4182001A						N/A
ProSet Intrafix® SafeSet	4182002A						N/A
ProSet Intrafix® SafeSet	4182097						N/A
ProSet Intrafix® SafeSet	4182098						N/A

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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						
ProSet Intrafix® Primeline	4187946						
ProSet Intrafix® SafeSet	4187989						
ProSet Intrafix® Primeline	4188020						
ProSet Intrafix® SafeSet	4188030						
ProSet Intrafix® SafeSet	4188110						
ProSet Intrafix® SafeSet	4188113						
ProSet Intrafix® SafeSet	4188114						
ProSet Intrafix® SafeSet	4188115						
ProSet Intrafix® SafeSet	4188116						
ProSet Intrafix® SafeSet	4188117						
ProSet Intrafix® Primeline	4187105						
ProSet Intrafix® SafeSet	4188120						
ProSet Intrafix® SafeSet	4188136						

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Schedule of Devices

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Article name	Article Number (under MDR application)						
ProSet Intrafix® SafeSet	4188137						N/A
ProSet Intrafix® SafeSet	4188140						N/A
ProSet Intrafix® SafeSet	4188155						N/A
ProSet Intrafix® SafeSet	4188159						N/A
ProSet Intrafix® SafeSet	4188170						N/A
ProSet Intrafix® SafeSet	4188530						N/A
ProSet Intrafix® SafeSet	4188531						N/A
ProSet Intrafix® SafeSet	4188540						N/A
ProSet Intrafix® SafeSet	4188550						N/A
ProSet Intrafix® SafeSet	4189109						N/A
ProSet Intrafix® SafeSet	4189582						N/A
ProSet Intrafix® SafeSet	4188119		G2S 012974 0457 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4062877		G1 012974 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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Schedule of Devices

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Intrafix® Primeline	4110001						N/A
Intrafix® Primeline	4110002						N/A
ProSet Intrafix®	4186914						N/A
Intrafix® Primeline	4060563						N/A
SafeSet	4063000A	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	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

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Article name	Article Number (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	
Infusomat® Plus Line SafeSet	8700220						
Infusomat® Plus Line	8700330						
Infusomat® Plus Line	8700320						N/A
ProSet Original Perfusor® Line	4092930						N/A
ProSet Original Perfusor® Line	4183945						N/A
ProSet Original Perfusor® Line	4183943						N/A
ProSet Original Perfusor® Line	4183941						N/A
ProSet Original Perfusor® Line	4183938						N/A
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 Perfusor® Line	4183933						
ProSet Original Perfusor® Line	4183935						
ProSet Original Perfusor® Line	4183936						
Infusomat® Plus Line	8700350CN	4039239000000086633	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-20						
Infusomat® Plus Line	8700360						
Infusomat® Space Line	8700193SP	403923900000008663B	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line							
Infusomat® Space Line	8270074SP	4039239000000086635	G1 012974 0607 NB0123	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							

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)						
Infusomat® Plus Line	8700370CN	403923900000008632X	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	8700400							
Infusomat® Plus Line	8700370							
Omnican® fine	9167641WE	40392390000001006ZF	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	9167650WE							
Omnican® fine	9167684WE							
Omnican® fine	9167820WE							
Omnican® fine	929G12S-03							
Omnican® fine	929G12S-41							
Omnican® fine	929G12S-43							
Omnican® fine	931G04S-03							
Omnican® fine	931G04S-41							
Omnican® fine	931G04S-43							
Omnican® fine	931G04SCN							
Omnican® fine	931G06S-03							
Omnican® fine	931G06S-41							
Omnican® fine	931G06S-43							
Omnican® fine	931G06S-AP							
Omnican® fine	931G06SCN1							
Omnican® fine	931G08S-03							
Omnican® fine	931G08S-41							
Omnican® fine	931G08S-43							
Omnican® fine	931G08S-44							
Omnican® fine	932G04S-03							
Omnican® fine	932G04S-41							
Omnican® fine	932G04S-43							
Omnican® fine	932G04S-AP							

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Article name	Article Number (under MDR application)	403923900000020742A	G1 012974 0607				N/A
Omnican® fine	932G04SCN						
Omnican® fine	932G04SCN1						
Omnican® fine	932G05SCN						
Omnican® fine	932G05SCN1						
Omnican® fine	932G06S-03						
Omnican® fine	932G06S-41						
Omnican® fine	932G06S-43						
Omnican® fine	932G06SCN						
Omnican® fine	932G06SCN1						
Omnican® fine	932P04						
Omnican® fine	932P05						
Omnican® fine	932P06						
Infusomat® Plus Line SafeSet	8700270	NB0123	NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700260C-20						
Infusomat® Plus Line SafeSet	8700260						
Original Perfusor® Line	8722865	G1 012974 0607	NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700410						
ProSet Infusomat® Space Line	4182190SP	403923900000086737	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4180639SP						
ProSet Infusomat® Space Line							
ProSet Infusomat® Space Line	4180020SP						

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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						

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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	4186486SP						
ProSet Infusomat® Space Line	8700095SP						
ProSet Infusomat® Space Line	8700110SP						

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Article name	Article Number (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 Infusomat® Space Line	4183878SP						N/A
ProSet Infusomat® Space Line	4180633SP						N/A
Infusomat® Space Line SafeSet	8250718SP						N/A
Infusomat® Space Line SafeSet	8700098SP						N/A
Infusomat® Space Line SafeSet	8701149SP						N/A
Infusomat® Space Line SafeSet	8700130SP						N/A
Infusomat® Space Line SafeSet	8700118SP						N/A
Infusomat® Space Line SafeSet	8250720SP						N/A
ProSet Infusomat® Space Line	4183918						N/A
ProSet Infusomat® Space Line	4183910						N/A
ProSet Infusomat® Space Line	4187789SP						N/A

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Schedule of Devices

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Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)						
ProSet Infusomat® Space Line	4185976SP						
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						

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)	40392390000008712W					
ProSet Infusomat® Space Line	4183901						
ProSet Infusomat® Space Line	4189981SP						
ProSet Infusomat® Space Line	4187377						
ProSet Infusomat® Space Line	4182189SP						
ProSet Infusomat® Space Line	8252659SP						
ProSet Infusomat® Space Line							
ProSet Original Perfusor® Line	4185687	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	
ProSet Original Perfusor® Line	4085129						
ProSet Original Perfusor® Line	8250803						
ProSet Original Perfusor® Line	4183971						
ProSet Original Perfusor® Line	4183970						
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							

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)						
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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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)	403923900000014792Z NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
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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ProSet Infusomat® Space Line	8252671SP						N/A
Sangofix®	4050192	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	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 Perusor® Line	8723001	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intuitive®	4094000N	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)

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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
	Comb-Stopper						
Comb-Stopper	4495209	40392390000008112C	NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	4495101R						
Safeflow Extension Set	4097154N	40392390000008152L	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	4097145N						
Safeflow Extension Set	4097154	40392390000008162N	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	409110H						
Safeflow	409100CN	403923900000027222S	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	409101H						
Safeflow	409100H	403923900000027222S	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
	4097148N						
Safeflow Extension Set	4097148N	403923900000027222S	G1 012974 0607 NB0123	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 SÜD Product Service GmbH (NB0123)	TUV SÜD 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 SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
IBSA FSH/LH	9161530S	4039239000001007ZH	NB0123	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Serofine™ needle	16441MS						N/A
Serofine™ needle	16443MS						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	P1400075					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	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	40392390000001217ZW	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 40 Duo	9161333V						
Omnifix® 100 Duo	9161376C						
Omnifix® 100 Duo	9161376V						
Omnifix® Luer Duo	4643011C	4039239000000077633	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						N/A

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Article name	Article Number (under MDR application)	403923900000077735	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Luer Duo	4643135C						
Omnifix® Luer Duo	4643135V						
Omnifix®-F Luer Duo	9161465V						
Omnifix® Luer Duo	4643161						
Omnifix® Luer Lock Solo	4617022V	4039239000000207022	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Luer Lock Solo	4617022V-03						
Omnifix® Luer Lock Solo	4617029V						
Omnifix® Luer Lock Solo	4617053V						
Omnifix® Luer Lock Solo	4617053V-03						
Omnifix® Luer Lock Solo	4617100CA						
Omnifix® Luer Lock Solo	4617100V						
Omnifix® Luer Lock Solo	4617100V-03						
Omnifix® Luer Lock Solo	4617207V						
Omnifix® Luer Lock Solo	4617207V-03						
Omnifix® Luer Lock Solo	4617304F						
Omnifix® Luer Lock Solo	4617509F						
Omnifix® Luer Lock Solo	4617509F-03						
Omnifix® Luer Lock Solo	4617510F-06						
Stericam® Safety Needle	4670002S-01						

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Article name	Article Number (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)	Basic UDI-DI (under MDR application)						
Sterican® Safety Needle	4670052S-01	4039239000000076834	GT 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670053S-01							N/A
Sterican® Safety Needle	4670055S-01							N/A
Sterican® Safety Needle	4670055SBR							N/A
Sterican®	4650018							N/A
Sterican®	4650034							N/A
Sterican®	4657500							N/A
Sterican®	4657519							N/A
Sterican®	4657527							N/A
Sterican®	4657543							N/A
Sterican®	4657624							N/A
Sterican®	4657640							N/A
Sterican®	4657667							N/A
Sterican®	4657675							N/A
Sterican®	4657683							N/A
Sterican®	4657705							N/A
Sterican®	4657799	N/A						
Sterican®	4657853	N/A						
Sterican®	4650021	N/A						
Sterican®	4665112	N/A						
Sterican®	4665120	N/A						
Sterican®	4665317	N/A						
Sterican®	4665406	N/A						
Sterican®	4665457	N/A						
Sterican®	4665465	N/A						
Sterican®	4665503	N/A						
Sterican®	4665511	N/A						
Sterican®	4665500	N/A						
Sterican®	4665635	N/A						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Sterican®	4665643	40392390000007742X	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican®	4665791						N/A
Sterican®	4667093						N/A
Sterican®	4667123						N/A
Sterican®	9180109						N/A
Sterican®	9180117						N/A
Sterican®	9186158						N/A
Sterican®	9186166						N/A
Sterican®	9186174						N/A
Sterican®	9186182						N/A
Injekt®-H Luer Duo	9166297	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022C	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022UA						N/A
Injekt® Luer Duo	4645022V						N/A
Injekt® Luer Duo	4645057C						N/A
Injekt® Luer Duo	4645057UA						N/A
Injekt® Luer Duo	4645057V						N/A
Injekt® Luer Duo	4645065C						N/A
Injekt® Luer Duo	4645103C						N/A
Injekt® Luer Duo	4645103UA						N/A
Injekt® Luer Duo	4645103V						N/A
Injekt® Luer Duo	4645200C	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645200UA						N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
Injekt® Luer Duo	4645200V						
Injekt® Luer Duo	4647220						N/A
Injekt®-F Luer Duo	9166033V						N/A
Sterican® Safety Needle	4670030SBR	403923900000076936	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670053SBR		NB0123				N/A
Contiplex® D	4898323	403923900000008522S	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898325		NB0123				N/A
Contiplex® D	4898305						N/A
Contiplex® D	4898308						N/A
Contiplex® D	4898311						N/A
Contiplex® D	4898335						N/A
Contiplex® D	4898305NR						N/A
NRFit®							N/A
Contiplex® D	4898335NR						N/A
NRFit®							N/A
Contiplex® D	4898311NR						N/A
NRFit®							N/A
Contiplex® D	4898323NR						N/A
NRFit®							N/A
Contiplex® D	4898325NR						N/A
NRFit®							N/A
Contiplex® D	4895819NCN						N/A
Contiplex® D	4894235NCN						N/A
Contiplex® D	4894391NCN						N/A
Contiplex® D	4898205	40392390000008532U	G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898211		NB0123				N/A
Contiplex® D	4898235						N/A
Contiplex® C	4898115	403923900000085000	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/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where 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)	NB0123	NB0123				N/A
Contiplex® C	4898130						
Contiplex® C NRF1®	4898115NR						
Contiplex® C NRF1®	4898130NR	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Ultraplex® 360	4892603-01						
Ultraplex® 360	4892603CN						
Ultraplex® 360	4892603NR-01						
Ultraplex® 360	4892605-01						
Ultraplex® 360	4892605CN						
Ultraplex® 360	4892605NR-01						
Ultraplex® 360	4892608-01						
Ultraplex® 360	4892608CN						
Ultraplex® 360	4892608NR-01						
Ultraplex® 360	4892610-01						
Ultraplex® 360	4892610CN						
Ultraplex® 360	4892610NR-01						
Ultraplex® 360	4892615-01						
Ultraplex® 360	4892615CN						
Ultraplex® 360	4892615NR-01	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® D	4892105						
Stimuplex® D	4892105-23						
Stimuplex® D	4892105CN						
Stimuplex® D	4892105NR						
Stimuplex® D	4892108						
Stimuplex® D	4892108-23						
Stimuplex® D	4892108CN						

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Schedule of Devices

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Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)		Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)					
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)

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)	NB0123					
Stimuplex® Ultra 360®	4892503-03						N/A
Stimuplex® Ultra 360®	4892503-04						N/A
Stimuplex® Ultra 360®	4892503-20						N/A
Stimuplex® 360®	4892503CN						N/A
Stimuplex® Ultra 360® NRFit®	4892503NR-01						N/A
Stimuplex® Ultra 360®	4892505-01						N/A
Stimuplex® Ultra 360®	4892505-03						N/A
Stimuplex® Ultra 360®	4892505-04						N/A
Stimuplex® Ultra 360®	4892505-20						N/A
Stimuplex® 360®	4892505CN						N/A
Stimuplex® Ultra 360® NRFit®	4892505NR-01						N/A
Stimuplex® Ultra 360®	4892508-01						N/A
Stimuplex® Ultra 360®	4892508-03						N/A
Stimuplex® Ultra 360®	4892508-04						N/A
Stimuplex® Ultra 360®	4892508-20						N/A
Stimuplex® 360®	4892508CN						N/A
Stimuplex® Ultra 360® NRFit®	4892508NR-01						N/A
Stimuplex® Ultra 360®	4892510-01						N/A
Stimuplex® Ultra 360®	4892510-03						N/A
Stimuplex® Ultra 360®	4892510-04						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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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)						
Stimuplex® Ultra 360®	4892510-20	4039239000000044ZG					N/A
Stimuplex® 360®	4892510CN						N/A
Stimuplex® Ultra 360® NRFit®	4892510NR-01						N/A
Stimuplex® Ultra 360®	4892515-01						N/A
Stimuplex® Ultra 360®	4892515-03						N/A
Stimuplex® Ultra 360®	4892515-04						N/A
Stimuplex® Ultra 360®	4892515-20						N/A
Stimuplex® 360®	4892515CN						N/A
Stimuplex® Ultra 360® NRFit®	4892515NR-01						N/A
Omnifix® Lock	4617003		G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617014		NB0123				N/A
Omnifix® Lock	4617021						N/A
Omnifix® Lock	4617508F-01						N/A
Original Perfusor® Syringe 20 ml	8728615		G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728615C	40392390000029923R	NB0123				N/A
Original Perfusor® Syringe 20 ml	8728623		G1 012974 0607	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728623C		NB0123				N/A
Original Perfusor® Syringe 20 ml	8728810F-04						N/A
Original Perfusor® Syringe 50 ml							N/A

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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)						
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							8728844F
Original Perfusor® Syringe 50 ml	8728844F-20	40392390000029923R	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-04							N/A
Original Perfusor® Syringe 50 ml	8728852F-06							N/A
Original Perfusor® Syringe 50 ml	8728852F-20							N/A
Original Perfusor® Syringe 50 ml	8728861F-04	403923900000207124	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-06							N/A
Original Perfusor® Syringe 50 ml	8728861F-20							N/A
Original Perfusor® Syringe 50 ml	8728845F-01							N/A
Original Perfusor® Syringe 50 ml	4450100	40392390000009993R	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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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)	4039239000001002Z3	G1 012974 0607 NB0123		TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450150						
Cystofix®	4450160						
Cystofix®	4450170						
Cystofix®	4450180	4039239000001002Z7	G1 022239 0080 NB0123 B.BRAUN MEDICAL SAS		TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450200						
Cystofix®	4450220						
Cystofix SG	4450410						
Cystofix SG	4450412	4039239000001001Z5	G1 022239 0080 NB0123 B.BRAUN MEDICAL SAS		TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix SG	4450414						
Cystofix SG	4450416						
Cystofix	4450010						
Cystofix	4450012	40392390000009272Y	G1 012974 0607 NB0123		TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450014						
Cystofix	4450016						
Cystofix	4450512						
Cystofix	4450514	40392390000009272Y	G1 012974 0607 NB0123		TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450516						
Cystofix	4450712						
Cystofix	4450714						
Cystofix	4450716	40392390000009272Y	G1 012974 0607 NB0123		TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450718						
Cystofix	4450720						
Cystofix	4450722						
Vasco® OP Powdered	6031510	40392390000009272Y	G1 012974 0607 NB0123		TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasco® OP Powdered	6031525						
Vasco® OP Powdered	6031532						
Vasco® OP Powdered	6031532						

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

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

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Article name	Article Number (under MDR application)	40392390000008052H	G1 012974 0607 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasco® OP Free	9208364						
Drainobag® Connection Tube Bayonet	5524913	403923900000290000	G2S 012974 0457 NB0123	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	4550404 4551001 4550200 4550250 4550200N 4550250N 4550404N
Filter Needle	415040						
Filter Hub	418021						
Filter Straw	415020						
Filter Straw	415021						
Sterifix® Filter Straw 4"	339171						
Sterifix® Filter Straw 1.75"	339170						
Sterifix® Filter Needle 1.5"	339169						

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)

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

Effective

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

UserName: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: 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
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UserName: Arico, Mareike (sommrde)
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Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10 Initiator: Anja Mai

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UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
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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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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