



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0607 Rev. 02

Manufacturer:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

Active medical devices for fluid management:

- Volumetric infusion pumps
- Infusion syringe pumps
- Elastomeric Pumps
- Control & organisation units and systems made out of it
- Irrigation Pump and accessories
- Enteral feeding pumps
- Pump for negative pressure wound therapy

Non-active medical devices (sterile and non-sterile) for:

- Injection, infusion, transfusion and nutrition
 - Anaesthesia, emergency, intensive and home care
 - Disinfecting, cleaning, rinsing
 - Irrigation
 - Cryotherapy
 - Configured customized sets
 - Medical devices for wound care
 - Medical Gloves
 - Sterile solutions (Irrigation Solutions)
- Sterile products for urology and gastroenterology:
- Catheters, catheter kits, drainage and irrigation kits, urological stents, nephrostomy kits, cystometry kits, accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713181267

Valid from:

2020-06-09

Valid until:

2024-05-26

Date,

2020-07-17

Christoph Dicks

Head of Certification/Notified Body

Certificato CE

Sistema Completo di Garanzia di Qualità

Direttiva 93/42/CEE concernente i Dispositivi Medici (MDD), Allegato II esclusa sezione (4)

(Dispositivi di Classe IIa, IIb o III)

N. G1 012974 0607 Rev. 02

Fabbricante:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Categoria(e) di prodotto:

Dispositivi medici attivi per la gestione dei fluidi

Dispositivi medici attivi per la gestione dei fluidi:

- Pompe volumetriche per infusione
- Pompe a siringa per infusione
- Pompe elastomeriche
- Unità e sistemi di controllo e organizzazione che ne derivano
- Pompa di irrigazione e accessori
- Pompe per nutrizione enterale
- Pompa per terapia delle ferite a pressione negativa

Dispositivi medici non attivi (sterili e non sterili) per:

- Iniezione, infusione, trasfusione e nutrizione
- Anestesia, emergenza, terapia intensiva e domiciliare
- Disinfezione, pulizia, risciacquo
- Irrigazione
- Crioterapia
- Set personalizzati configurati
- Dispositivi medici per la cura delle ferite
- Guanti medici
- Soluzioni sterili (Soluzioni per l'irrigazione)

Prodotti sterili per urologia e gastroenterologia:

- Cateteri, kit di cateteri, kit di drenaggio e irrigazione, stent **urologici**, kit per nefrostomia, kit per cistometria, accessori

L'Organismo Notificato TÜV SÜD Product Service GmbH dichiara con la presente che il fabbricante sopra menzionato ha implementato un Sistema di Gestione della Qualità per la progettazione, la produzione e il controllo finale dei rispettivi dispositivi/categorie di dispositivi in conformità all'Allegato II della MDD. Questo Sistema di Gestione della Qualità soddisfa i requisiti della Direttiva ed è soggetto a sorveglianza periodica. Per la commercializzazione dei dispositivi di Classe III è necessario un certificato aggiuntivo per l'Allegato II (4). Vedere anche note sul retro.

Report n.:

713181267

Valido dal:

09-06-2020

Valido fino al:

26-05-2024

Data, 17-07-2020



Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Your reference/letter of	Our reference/name	Tel. extension/Email	Date	Page
12974	713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	medical_devices@tuvsud.com	2024-06-22	1 of 43

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 012974 0657 Rev. 02

Reference: 713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000000201

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Zertifizierstelle für Medizinprodukte /
Certification Body for Medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 012974 0657 Rev. 02

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-06-22

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 930131

Jürgen Kunte

Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 929494

Florian Grentzebach
Application Reviewer

Effective



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Perfusor® compactplus	8717030	N/A	4039239000000038ZM	class IIb	G1 012974 0607 Rev. 02 NB0123
Infusomat® compactplus	8717050	N/A	403923900000005352B	class IIb	G1 012974 0607 Rev. 02 NB0123
OnlineSuite	876100	N/A	403923900000005552H	class IIb	G1 012974 0607 Rev. 02 NB0123
Spaceplus Perfusor®	8719030	N/A	403923900000007562V	class IIb	G1 012974 0607 Rev. 02 NB0123
Spaceplus Infusomat®	8719050	N/A	403923900000007552T	class IIb	G1 012974 0607 Rev. 02 NB0123
Infusomat® compactplus P	8717070	N/A	403923900000007492Y	class IIb	G1 012974 0607 Rev. 02 NB0123
Sangofix® Air	4116011F	N/A	40392390000000039ZP	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnifix® Lock	4617006	N/A	40392390000000044ZG	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnican fine	932M04SE	N/A	403923900000018743B	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnican fine	931M08SE	N/A			
Drainobag® 600 V	5523606	N/A	403923900000007973B	class IIa	G1 012974 0607 Rev. 02 NB0123
Drug Library Manager Spaceplus	876203	N/A	4039239000000169539	class IIb	G1 012974 0607 Rev. 02 NB0123
Drug Library Manager Spaceplus	876209	N/A	4039239000000169539	class IIb	G1 012974 0607 Rev. 02 NB0123
GLYCINE 1,5 % B. BRAUN	FR29914	N/A	4039239000000249638	class IIb	G1 012974 0607 Rev. 02 NB0123
GLYCINE 1,5 % B. BRAUN	FREU914	N/A			
GLYCINE 1,5 % B. BRAUN	FREU934	N/A			
GLYCINE 1,5 % B. BRAUN	FREU954	N/A			

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

Freigabe bestätigt: Dokument Richtig zugeordnet / vollständig und lesbar

Print Date - Gedruckt am: 2024-07-17 15:00 (CET)



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
GLYCINE 1,5 % B. BRAUN	FREU974	N/A			
NaCl 0,9 % B. BRAUN	FREU850	N/A	403923900000250128	class IIb	G1 012974 0607 Rev. 02 NB0123
NaCl 0,9 % B. BRAUN	FREU910	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	N/A	40392390000026312N	class IIb	G1 012974 0607 Rev. 02 NB0123
NaCl 0,9 % B. BRAUN	3637006	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			
NaCl 0,9 % B. BRAUN	3570130	N/A			
NaCl 0,9 % B. BRAUN	3570140	N/A			
NaCl 0,9 % B. BRAUN	0066570E	N/A			
NaCl 0,9 % B. BRAUN	3521370	N/A			
NaCl 0,9 % B. BRAUN	3570150	N/A			
NaCl 0,9 % B. BRAUN	3570160	N/A			
NaCl 0,9 % B. BRAUN	3570170	N/A			
NaCl 0,9 % B. BRAUN	0066569E	N/A			
NaCl 0,9 % B. BRAUN	3570110	N/A			
Vitulia	450268	N/A	40392390000025022A	class IIb	G1 012974 0607 Rev. 02 NB0123
Vitulia	450272	N/A			
NaCl 0,9 % B. BRAUN	3570300	N/A			
NaCl 0,9 % B. BRAUN	3570301	N/A			
NaCl 0,9 % B. BRAUN	3570310	N/A			
NaCl 0,9 % B. BRAUN	3570330	N/A			
NaCl 0,9 % B. BRAUN	391858	N/A			
NaCl 0,9 % B. BRAUN	3570350	N/A			
NaCl 0,9 % B. BRAUN	3570360	N/A			
NaCl 0,9 % B. BRAUN	3570340	N/A			
NaCl 0,9 % B. BRAUN	3637010	N/A			
NaCl 0,9 % B. BRAUN	391859	N/A			
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% Solution d'irrigation	497429	N/A			
NaCl 0,9 % B. BRAUN	3570460	N/A	40392390000026302L	class IIb	G1 012974 0607 Rev. 02 NB0123
NaCl 0,9 % B. BRAUN	3570470	N/A			
NaCl 0,9 % B. BRAUN	3570480	N/A			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
RINGER B. BRAUN	FREU864	N/A	40392390000025062J	class IIb	G1 012974 0607 Rev. 02 NB0123
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	N/A	40392390000026342U	class IIb	G1 012974 0607 Rev. 02 NB0123
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			
RINGER B. BRAUN	3570060	N/A			
RINGER B. BRAUN	3570611	3570490	40392390000026322Q	class IIb	G1 012974 0607 Rev. 02 NB0123
RINGER B. BRAUN	3570610	3570500			
RINGER B. BRAUN	3570614	3570510			
RINGER B. BRAUN	3570612	3570520			
RINGER B. BRAUN	3570613	3570530	40392390000026332S	class IIb	G1 012974 0607 Rev. 02 NB0123
Aqua B. Braun	FREU812	N/A	40392390000024973A	class IIb	G1 012974 0607 Rev. 02 NB0123
Aqua B. Braun	FREU852	N/A			
Aqua B. Braun	FREU912	N/A			
Aqua B. Braun	FREU932	N/A			
Aqua B. Braun	387872	N/A	40392390000026272X	class IIb	G1 012974 0607 Rev. 02 NB0123
Aqua B. Braun	387873	N/A			
Aqua B. Braun	387874	N/A			
Aqua B. Braun	442464	N/A			
Aqua B. Braun	442465	N/A			
Aqua B. Braun	442466	N/A			
Sterile Water for Irrigation	3637011	N/A			
Aqua B. Braun	3521380	N/A	403923900000262933	class IIb	G1 012974 0607 Rev. 02 NB0123
Aqua B. Braun	3521390	N/A			
Aqua B. Braun	3553949	N/A			
Aqua B. Braun	3553957	N/A			
Aqua B. Braun	0065729E	N/A			
Aqua B. Braun	0066571E	N/A			
Aqua B. Braun	0069415E	N/A			
Aqua B. Braun	0082423E	N/A			
Aqua B. Braun	0082479E	N/A			
Sterile Water for Irrigation	3637007	N/A			
Perifix® Catheter Connector	4513800	N/A	403923900000238732	class IIa	G1 012974 0607 Rev. 02
Perifix® Catheter Connector	4513801	N/A			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Perifix® Catheter Connector NRFit	4513800N-01	N/A			NB0123
Perifix® Catheter Connector NRFit	4513801N-01	N/A			
Infusomat® Space	8713050	N/A	40392390000007462S	class IIb	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space P	8713070	N/A	40392390000007472U	class IIb	G1 012974 0607 Rev. 02 NB0123
Perfusor® Space	8713030	N/A	40392390000007482W	class IIb	G1 012974 0607 Rev. 02 NB0123
Enteroport® plus	8710355	N/A	40392390000007452Q	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Plus Line SafeSet	8700200	N/A	40392390000008622V	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Plus Line SafeSet	8700200-20	N/A			
Infusomat® Plus Line SafeSet	8700210	N/A			
Infusomat® Plus Line	8700310	N/A			
Infusomat® Plus Line	8700310-20	N/A			
Infusomat® Plus Line	8700310CN	N/A			
Cyto-Set® Infusomat® Space	8250414SP	N/A	40392390000007832Y	class IIa	G1 012974 0607 Rev. 02 NB0123
Cyto-Set® Infusomat® Space	8250817SP	N/A			
Cyto-Set® Infusomat® Space	8250820SP	N/A			
Cyto-Set® Infusomat® Space	8250917SP	N/A			
Cyto-Set® Infusomat® Space	8250920SP	N/A			
Cyto-Set® Infusomat® Space	835414SP	N/A			
Cyto-Set® Infusomat® Space	835817SP	N/A			
Cyto-Set® Infusomat® Space	835820SP	N/A			
Cyto-Set® Infusomat® Space	835917SP	N/A			
Cyto-Set® Infusomat® Space	835920SP	N/A			
Cyto-Set® Infusomat® plus	8700420	N/A			
Cyto-Set® Infusomat® plus	8700430	N/A			
Cyto-Set® Infusomat® plus	8700440	N/A			
Cyto-Set® Infusomat® plus	8700450	N/A			
Cyto-Set® Infusomat® plus	8700460	N/A			
Cyto-Set® Infusomat® plus	8700470	N/A			
Cyto-Set® Infusomat® plus	8700480	N/A			
Cyto-Set® Infusomat® plus	8700490	N/A			
Cyto-Set® Line	A2581NF	N/A	40392390000007843Z	class IIa	G1 012974 0607 Rev. 02
Cyto-Set® Line	A2582NF	N/A			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Cyto-Set® Mix	A2900N	N/A			NB0123
Cyto-Set® Mix	A2903N	N/A			
Cyto-Set® Mix	A2906N	N/A			
Cyto-Set® Mix	A2907N	N/A			
Cyto-Set® Mix	A2908N	N/A			
Stimuplex® A	4894251	N/A	40392390000008602R	class IIa	G1 012974 0607 Rev. 02 NB0123
Stimuplex® A	4894539	N/A			
Stimuplex® A	4894367	N/A			
Stimuplex® A	4894502	N/A			
Stimuplex® A	4894375	N/A			
Stimuplex® A	4894260	N/A			
Stimuplex® A	4894278	N/A			
Stimuplex® A	4894278NR	N/A			
Stimuplex® A	4894375NR	N/A			
Stimuplex® A	4894260NR	N/A			
Stimuplex® A	4894367NR	N/A			
Stimuplex® A	4894539NR	N/A			
Stimuplex® A	4894502NR	N/A			
Stimuplex® A	4894251 NR	N/A			
Easypump® II LT 60-12	4540002	N/A	40392390000023452J	class IIb	G1 012974 0607 Rev. 02 NB0123
Easypump® II LT 60-12	4540002-07	N/A			
Easypump® II LT 60-12	4540002-20	N/A			
Easypump® II LT 500-12.5	4540003	N/A			
Easypump® II LT 500-12.5	4540003-07	N/A			
Easypump® II LT 500-12.5	4540003-20	N/A			
Easypump® II LT 80-16	4540004	N/A			
Easypump® II LT 80-16	4540004-07	N/A			
Easypump® II LT 80-16	4540004-20	N/A			
Easypump® II LT 125-25	4540006	N/A			
Easypump® II LT 125-25	4540006-07	N/A			
Easypump® II LT 125-25	4540006-20	N/A			
Easypump® II LT 270-27	4540008	N/A			
Easypump® II LT 270-27	4540008-07	N/A			
Easypump® II LT 270-27	4540008-20	N/A			
Easypump® II LT 60-30	4540010	N/A			
Easypump® II LT 60-30	4540010-07	N/A			
Easypump® II LT 60-30	4540010-20	N/A			
Easypump® II LT 120-30	4540012	N/A			
Easypump® II LT 120-30	4540012-07	N/A			
Easypump® II LT 120-30	4540012-20	N/A			
Easypump® II LT 400-40	4540014	N/A			
Easypump® II LT 400-40	4540014-07	N/A			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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			
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	4540022-20	N/A			
Easypump® II LT 270-68	4540026	N/A			
Easypump® II LT 270-68	4540026-07	N/A			
Easypump® II LT 270-68	4540026-20	N/A			
Easypump® II LT 400-100	4540028	N/A			
Easypump® II LT 400-100	4540028-07	N/A			
Easypump® II LT 400-100	4540028-20	N/A			
Easypump® II LT 270-135	4540032	N/A			
Easypump® II LT 270-135	4540032-07	N/A			
Easypump® II LT 270-135	4540032-20	N/A			
Easypump® II ST 100-0,5	4540040	N/A			
Easypump® II ST 100-0,5	4540040-07	N/A			
Easypump® II ST 100-0,5	4540040-20	N/A			
Easypump® II ST 250-0,5	4540042	N/A			
Easypump® II ST 250-0,5	4540042-07	N/A			
Easypump® II ST 250-0,5	4540042-20	N/A			
Easypump® II ST 50-1	4540044	N/A			
Easypump® II ST 50-1	4540044-07	N/A			
Easypump® II ST 50-1	4540044-20	N/A			
Easypump® II ST 100-1	4540046	N/A			
Easypump® II ST 100-1	4540046-07	N/A			
Easypump® II ST 100-1	4540046-20	N/A			
Easypump® II ST 250-1	4540048	N/A			
Easypump® II ST 250-1	4540048-07	N/A			
Easypump® II ST 250-1	4540048-20	N/A			
Easypump® II ST 250-1,5	4540050	N/A			
Easypump® II ST 250-1,5	4540050-07	N/A			
Easypump® II ST 250-1,5	4540050-20	N/A			
Easypump® II ST 400-2	4540052	N/A			
Easypump® II ST 400-2	4540052-07	N/A			
Easypump® II ST 400-2	4540052-20	N/A			
Easypump® II ST 500-2	4540054	N/A			
Easypump® II ST 500-2	4540054-07	N/A			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Easpump® II ST 500-2	4540054-20	N/A			
Easpump® II ST 100-2	4540056	N/A			
Easpump® II ST 100-2	4540056-07	N/A			
Easpump® II ST 100-2	4540056-20	N/A			
Easpump® II ST 400-4	4540058	N/A			
Easpump® II ST 400-4	4540058-07	N/A			
Easpump® II ST 400-4	4540058-20	N/A			
Spinal Introducer	4505000-13	4505000	403923900000085836	class IIa	G1 012974 0607
Spinal Introducer	4500059-13	4500059			Rev. 02 NB0123
Contiplex® S 360	4898650CN	N/A	40392390000008542W	class IIa	G1 012974 0607 Rev. 02 NB0123
Contiplex® S 360	4898610CN	N/A			
Contiplex® S 360	4898615CN	N/A			
Contiplex® S Ultra 360®	4898650-01	N/A			
Contiplex® S Ultra 360®	4898610-01	N/A			
Contiplex® S Ultra 360®	4898615-01	N/A			
Contiplex® S Ultra 360®	4898650-27	N/A			
Contiplex® S Ultra 360®	4898610-27	N/A			
Contiplex® S Ultra 360®	4898615-27	N/A			
Perifix Filter	4515501	N/A	403923900000238834	class IIa	G1 012974 0607 Rev. 02 NB0123
Perifix Filter NRFit	4515501N-01	N/A			
Contiplex® S Ultra 360® NRFit®	4898650NR-27	N/A	40392390000008542W	class IIa	G1 012974 0607 Rev. 02 NB0123
Contiplex® S Ultra 360® NRFit®	4898610NR-27	N/A			
Contiplex® S Ultra 360® NRFit®	4898615NR-27	N/A			
Contiplex® Tuohy Ultra 360® NRFit®	4898704NR-01	N/A			
Contiplex® Tuohy Ultra 360® NRFit®	4898705NR-01	N/A			
Contiplex® Tuohy Ultra 360® NRFit®	4898710NR-01	N/A			
Contiplex® Tuohy Ultra 360® NRFit®	4898715NR-01	N/A			
Contiplex® Tuohy Ultra 360®	4898704-01	N/A			
Contiplex® Tuohy Ultra 360®	4898705-01	N/A			
Contiplex® Tuohy Ultra 360®	4898710-01	N/A			
Contiplex® Tuohy Ultra 360®	4898715-01	N/A			
Contiplex® Tuohy Ultra 360®	4898704-27	N/A			
Contiplex® Tuohy Ultra 360®	4898705-27	N/A			
Contiplex® Tuohy Ultra 360®	4898710-27	N/A			
Contiplex® Tuohy Ultra 360®	4898715-27	N/A			
Discofix®	4099117	N/A	40392390000007582Z	class IIa	G1 012974 0607



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Discofix®	4095111	N/A			Rev. 02 NB0123
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			
Discofix®	4099010	N/A			
Discofix®	4095210	15809			
Nutritub® ENFit® intestinal	9246605	9246584 9246586	40392390000029463J	class IIa	G1 019717 0032 Rev. 00 NB0123 B. Braun Avitum Italy S.p.A.**
Nutritub® ENFit® intestinal	9246604	9246576 9246578			
Nutritub® Gastral Basic ENFit®	9246603	9246519	40392390000008172Q	class IIa	G1 019717 0032 Rev. 00 NB0123 B. Braun Avitum Italy S.p.A.**
Nutritub® Gastral Basic ENFit®	9246602	9246518			
Nutritub® Gastral Basic ENFit®	9246601	9246516 9246550			
Nutritub® Gastral Basic ENFit®	9246600	9246515 9246592			
Nutritub® Gastral Basic ENFit®	9246599	9246514			
Nutritub® Gastral Basic ENFit®	9246598	9246513			
Nutritub® Gastral Basic ENFit®	9246597	9246541 9246543			
Nutritub® Gastral Basic ENFit®	9246596	9246512			
Nutritub® Gastral Basic ENFit®	9246595	9246517 9246525 9246533 9246535			

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Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Nutritub® Gastral Basic ENFit®	9246594	9246509 9246511			
Nutritub® Gastral Basic ENFit®	9246593	9246508			
Infusomat® Space Line	8250832SP	8250833SP	403923900000086839	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space Line	8250834SP	8250835SP			
IN-Stopper	4238010	N/A	403923900000028583L	class IIa	G1 012974 0607 Rev. 02 NB0123
IN-Stopper	4238011	N/A			
Combi-Stopper	4495101	N/A	40392390000008112C	class IIa	G1 012974 0607 Rev. 02 NB0123
Combi-Stopper	4495152	N/A			
Combifix Adapter	5206634	N/A	40392390000008122E	class IIa	G1 012974 0607 Rev. 02 NB0123
Combifix Adapter	5206642	N/A			
Original Perfusor® Line	87229910	N/A	40392390000008702U	class IIa	G1 012974 0607 Rev. 02 NB0123
Pleurofix® No. 1	4461002	N/A	40392390000007902V	class IIa	G1 012974 0607 Rev. 02 NB0123
Pleurofix® No. 2	4461037	N/A			
Seldinger Introducer Needle	4206096	N/A	40392390000007442N	class IIa	G1 012974 0607 Rev. 02 NB0123
Seldinger Introducer Needle	4206100	N/A			
Injekt® 40 Duo	9166432C	N/A	4039239000000121823	class IIa	G1 012974 0607 Rev. 02 NB0123
Injekt® 40 Duo	9166432V	N/A			
Introcane Safety® 3	4251127-01	N/A	40392390000007652W	class IIa	G1 012974 0607 Rev. 02 NB0123
Introcane Safety® 3	4251127-03	N/A			
Introcane Safety® 3	4251127-04	N/A			
Introcane Safety® 3	4251127IN	N/A			
Introcane Safety® 3	4251127JP	N/A			
Introcane Safety® 3	4251128-01	N/A			
Introcane Safety® 3	4251128-03	N/A			
Introcane Safety® 3	4251128-04	N/A			
Introcane Safety® 3	4251128IN	N/A			
Introcane Safety® 3	4251128JP	N/A			
Introcane Safety® 3	4251129-01	N/A			
Introcane Safety® 3	4251129-03	N/A			
Introcane Safety® 3	4251129-04	N/A			
Introcane Safety® 3	4251129JP	N/A			
Introcane Safety® 3	4251130-01	N/A			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Introcan Safety® 3	4251130-03	N/A			
Introcan Safety® 3	4251130-04	N/A			
Introcan Safety® 3	4251130IN	N/A			
Introcan Safety® 3	4251130JP	N/A			
Introcan Safety® 3	4251131-01	N/A			
Introcan Safety® 3	4251131-03	N/A			
Introcan Safety® 3	4251131-04	N/A			
Introcan Safety® 3	4251131JP	N/A			
Introcan Safety® 3	4251132-01	N/A			
Introcan Safety® 3	4251132-03	N/A			
Introcan Safety® 3	4251132-04	N/A			
Introcan Safety® 3	4251132IN	N/A			
Introcan Safety® 3	4251133-01	N/A			
Introcan Safety® 3	4251133-03	N/A			
Introcan Safety® 3	4251133-04	N/A			
Introcan Safety® 3	4251134-01	N/A			
Introcan Safety® 3	4251134-03	N/A			
Introcan Safety® 3	4251134-04	N/A			
Introcan Safety® 3	4251135-01	N/A			
Introcan Safety® 3	4251135-03	N/A			
Introcan Safety® 3	4251135-04	N/A			
Introcan Safety® 3	4251136-01	N/A			
Introcan Safety® 3	4251136-03	N/A			
Introcan Safety® 3	4251136-04	N/A			
Introcan Safety® 3	4251137-01	N/A			
Introcan Safety® 3	4251137-03	N/A			
Introcan Safety® 3	4251137-04	N/A			
Introcan Safety® 3	4251144-01	N/A			
Drainobag® Connection Tube Bayonet	5524913	U2170701	40392390000008052H	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space Line	8700036SP	N/A	403923900000086737	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space Line	8700435SP	N/A			
Infusomat® Space Line SafeSet	8701148SP	N/A			
Infusomat® Space Line	8270066SP-01	8270066SP	403923900000086635	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space Line	8270066SP-26	N/A			
Infusomat® Plus Line	8700350-01	N/A	403923900000086533	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Plus Line	8700350-26	N/A			
Enteroport® ENFit® Set	8721739	8721748 8721749	403923900000263732	class IIa	G1 019717 0032 Rev. 00



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		8721750 8721688 8721726 8721734 8721735 8721736 8721737 8721742			NB0123 B. Braun Avitum Italy S.p.A. **
Enteroport® ENFit® Set	8721738	8721744 8721745 8721746 8721747			
Double Spike Adaptor	4054032	N/A	40392390000007883A	class IIa	G1 012974 0607 Rev. 02 NB0123
Extension Line, Type: Alargadera	4094603	N/A			
In-line injection tubing	4247116	N/A			
LS-3 Connector	4053753	N/A	403923900000078738	class IIa	G1 012974 0607 Rev. 02 NB0123
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			
ProSet Cyto-Set®	8250266	N/A	40392390000007832Y	class IIa	G1 012974 0607 Rev. 02 NB0123
ProSet Cyto-Set®	8250366	N/A			
ProSet Cyto-Set®	8250370	N/A			
ProSet Cyto-Set® Infusomat® Space	8250455SP	N/A			
ProSet Cyto-Set® Infusomat® Space	8250650SP	N/A			
ProSet Cyto-Set® Infusomat® Space	8250655SP	N/A			
ProSet Cyto-Set® Infusomat® Space	8250818SP	N/A			
ProSet Cyto-Set® Infusomat® Space	8250866SP	N/A			
ProSet Cyto-Set® Infusomat® Space	8250915SP	N/A			
ProSet Cyto-Set® Infusomat® Space	8250966SP	N/A			
ProSet Cyto-Set® Infusomat® Space	8250970SP	N/A			

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Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ProSet Cyto-Set® Infusomat® Space	8250980SP	N/A			
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	8352075SP	N/A			
ProSet Cyto-Set® Mix	4182700	N/A	403923900000078432	class IIa	G1 012974 0607 Rev. 02 NB0123
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			

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Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ProSet Cyto-Set® Line	4188093	N/A			
ProSet Cyto-Set® Mix	4188925	N/A			
ProSet Cyto-Set® Mix	4188926	N/A			
ProSet Cyto-Set® Pump Adapter	4182704	N/A	403923900000078534	class IIa	G1 012974 0607 Rev. 02 NB0123
Cyto-Set® Pump Adapter	A167350	N/A			
Dosifix®	4037011	N/A	40392390000008192U	class IIa	G1 012974 0607 Rev. 02 NB0123
Dosifix®	4037012	N/A			
Dosifix®	4037013	N/A			
Dosifix®	4037032	N/A			
Dosifix®	4037031	N/A	40392390000008202D	class IIa	G1 012974 0607 Rev. 02 NB0123
Heidelberger Extension Tubing	4033809	N/A	403923900000078636	class IIa	G1 012974 0607 Rev. 02 NB0123
Heidelberger Extension Tubing	4034589	N/A			
Heidelberger Extension Tubing	4038703	N/A			
Heidelberger Extension Tubing	4055128	N/A			
Heidelberger Extension Tubing	4055136	N/A			
Extension Line, Type: Heidelberger	4097130	N/A			
Extension Line, Type: Heidelberger	4097173	N/A			
Extension Line, Type: Heidelberger	4097190	N/A			
Extension Line, Type: Heidelberger	4097262	N/A			
Extension Line, Type: Heidelberger	4097290	N/A			
Extension Line, Type: Heidelberger	4097291	N/A			
Extension Line, Type: Heidelberger	4097300	N/A			
Extension Line, Type: Heidelberger	4097408	N/A			
Introcane® Certo	4055764	N/A	40392390000007612N	class IIa	G1 012974 0607 Rev. 02 NB0123
Introcane® Certo	4251300	N/A			
Introcane® Certo	4251318	N/A			
Introcane® Certo	4251326	N/A			
Introcane® Certo	4251334	N/A			
Introcane® Certo	4251342	N/A			
Introcane® Certo	4251350	N/A			
Introcane® Certo	4251369	N/A			



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Introcan®	4252071B	N/A			
Introcan®	4252098B	N/A			
Introcan®	4252110B	N/A			
Introcan®	4252136B	N/A			
Introcan®	4252160B	N/A			
Introcan®	4252217B	N/A			
Introcan®	4252322B	N/A			
Introcan®-W Certo	4253302	N/A			
Introcan®-W Certo	4253310	N/A			
Introcan®-W Certo	4253329	N/A			
Introcan®-W Certo	4253337	N/A			
Introcan®-W Certo	4253345	N/A			
Introcan®-W Certo	4253353	N/A			
Introcan®-W Certo	4253361	N/A			
Introcan®-W	4254074B	N/A			
Introcan®-W	4254090B	N/A			
Introcan®-W	4254112B	N/A			
Introcan®-W	4254139B	N/A			
Introcan®-W	4254171B	N/A			
Introcan®-W	4254210B	N/A			
Introcan®-W	4254325B	N/A			
Discofix® C Safeflow	16494CCN	N/A	40392390000007602L	class IIa	G1 012974 0607 Rev. 02 NB0123
Discofix® C Safeflow	16495CCN	N/A			
Discofix® C Safeflow	16501CCN	N/A			
Discofix® C Safeflow	16500CCN	N/A			
Discofix® C Safeflow	16540CCN	N/A			
Discofix® C Safeflow	16520CCN	N/A			
Intrapur® Neonat	4099451	N/A	40392390000008082P	class IIa	G1 012974 0607 Rev. 02 NB0123
Intrapur®	4093216	N/A			
Sterifix®	4184637	N/A			
Sterifix®	4099354	N/A			
Sterifix®	4099303	N/A			
Sterifix® Neonat	4099257	N/A			
Intrapur®	4099713	4099753			
Intrapur® Lipid	4099703	4099850			
Intrapur®	4183916	N/A			
Intrapur®	4099800	N/A			
Intrapur®	4099702	N/A			
Intrapur® Neonat Lipid	4099460	N/A			
Discofix® C	16500CSF-1	N/A	403923900000075933	class IIa	G1 012974 0607 Rev. 02 NB0123
Discofix® C	16540C	N/A			
Discofix® C	16494C	N/A			



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Discofix® C	16801C	N/A			
Discofix® C	16494CSF	N/A			
Discofix® C	16800C	N/A			
Discofix® C	16504C	N/A			
Discofix® C	16501C	N/A			
Discofix® C	16760C	N/A			
Discofix® C	16495CSF	N/A			
Discofix® C	16613C	N/A			
Discofix® C	16609C	N/A			
Discofix® C	16503C	N/A			
Discofix® C	16605C	N/A			
Discofix® C	16751C	N/A			
Discofix® C	16502C	N/A			
Discofix® C	16612C	N/A			
Discofix® C	16740C	N/A			
Discofix® C	16551CSF	N/A			
Discofix® C	16497C	N/A			
Discofix® C	16610C	N/A			
Discofix® C	16540CSF	N/A			
Discofix® C	16720C	N/A			
Discofix® C	16520CSF	N/A			
Discofix® C	16520C	N/A			
Discofix® C	16701C	N/A			
Discofix® C	16496C	N/A			
Discofix® C	16501CSF-1	N/A			
Discofix® C	RU16496C	N/A			
Discofix® C	RU16495C	N/A			
Discofix® C	CN16496C	N/A			
Discofix® C	RU16494C	N/A			
Discofix® C	EC16494C	N/A			
Discofix® C	CN16494C	N/A			
Discofix® C	16611C	N/A			
Discofix® C	16608C	N/A			
Discofix® C	16600C	N/A			
Discofix® C	16501CSF	N/A			
Pleuracan®	4462556	N/A	40392390000007922Z	class IIa	G1 012974 0607 Rev. 02 NB0123
Pleuracan® B	4462505	N/A			
Pleuracan® Back-Check Valve	4462564	N/A	403923900000079333	class IIa	G1 012974 0607 Rev. 02 NB0123
Drainobag® Lock 600	5523682	N/A	403923900000281736	class IIa	G1 012974 0607



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
					Rev. 02 NB0123
Discofix® C	16700C	N/A	403923900000075933	class IIa	G1 012974 0607 Rev. 02 NB0123
Discofix® C	16500C	N/A			
Discofix® C	16495C	N/A			
Discofix® C	16560CSF	N/A			
Discofix® C	16901C	N/A			
Discofix® C	16615C	N/A			
Discofix® C	16560C	N/A			
Discofix® C	16494C-01	N/A			
Discofix® C	16500CSF	N/A			
Discofix® C	16551C	N/A			
Discofix® C	16900C	N/A			
Discofix® C	BR16496C	N/A			
Discofix® C	16614C	N/A			
Heidelberger Extension Tubing	4052145	N/A	40392390000026953G	class IIa	G1 012974 0607 Rev. 02 NB0123
Heidelberger Extension Tubing	4052197	N/A			
Heidelberger Extension Tubing	4052197H	N/A			
Introcane Safety®	4251601-01	N/A	40392390000007632S	class IIa	G1 012974 0607 Rev. 02 NB0123
Introcane Safety®	4251601-03	N/A			
Introcane Safety®	4251601-04	N/A			
Introcane Safety®	4251601JP	N/A			
Introcane Safety®	4251607-01	N/A			
Introcane Safety®	4251607-03	N/A			
Introcane Safety®	4251607-04	N/A			
Introcane Safety®	4251607JP	N/A			
Introcane Safety®-W	4251614-01	N/A			
Introcane Safety®-W	4251614-03	N/A			
Introcane Safety®-W	4251614-04	N/A			
Introcane Safety®-W	4251614JP	N/A			
Introcane Safety®	4251620-01	N/A			
Introcane Safety®	4251621-01	N/A			
Introcane Safety®	4251622-01	N/A			
Introcane Safety®	4251623-01	N/A			
Introcane Safety®	4251628-01	N/A			
Introcane Safety®	4251628-03	N/A			
Introcane Safety®	4251628-04	N/A			
Introcane Safety®	4251628JP	N/A			
Introcane Safety®	4251644-01	N/A			
Introcane Safety®	4251644-03	N/A			
Introcane Safety®	4251644-04	N/A			
Introcane Safety®	4251644JP	N/A			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Introcan Safety®	4251652-01	N/A			
Introcan Safety®	4251652-03	N/A			
Introcan Safety®	4251652-04	N/A			
Introcan Safety®	4251652JP	N/A			
Introcan Safety®	4251679-01	N/A			
Introcan Safety®	4251679-03	N/A			
Introcan Safety®	4251679-04	N/A			
Introcan Safety®	4251679JP	N/A			
Introcan Safety®	4251687-01	N/A			
Introcan Safety®	4251687-03	N/A			
Introcan Safety®	4251687-04	N/A			
Introcan Safety®	4251687JP	N/A			
Introcan Safety®	4251695-01	N/A			
Introcan Safety®	4251695-03	N/A			
Introcan Safety®	4251695-04	N/A			
Introcan Safety®	4251695JP	N/A			
Introcan Safety®	4251709-01	N/A			
Introcan Safety®	4251709-03	N/A			
Introcan Safety®	4251709-04	N/A			
Introcan Safety®	4251709JP	N/A			
Introcan Safety®	4251717-01	N/A			
Introcan Safety®	4251717-03	N/A			
Introcan Safety®	4251717-04	N/A			
Introcan Safety®	4251890-01	N/A			
Introcan Safety®	4251890-03	N/A			
Introcan Safety®	4251890-04	N/A			
Introcan Safety®	4252500-01	N/A			
Introcan Safety®	4252500-03	N/A			
Introcan Safety®	4252500-04	N/A			
Introcan Safety®	4252519-01	N/A			
Introcan Safety®	4252519-03	N/A			
Introcan Safety®	4252519-04	N/A			
Introcan Safety®	4252520-01	N/A			
Introcan Safety®	4252527-01	N/A			
Introcan Safety®	4252527-03	N/A			
Introcan Safety®	4252535-01	N/A			
Introcan Safety®	4252535-03	N/A			
Introcan Safety®	4252535-04	N/A			
Introcan Safety®	4252543-01	N/A			
Introcan Safety®	4252551-01	N/A			
Introcan Safety®	4252551-03	N/A			
Introcan Safety®	4252551-04	N/A			

Effective



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Introcan Safety®	4252560-01	N/A			
Introcan Safety®	4252560-03	N/A			
Introcan Safety®	4252560-04	N/A			
Introcan Safety®	4252578-01	N/A			
Introcan Safety®	4252578-03	N/A			
Introcan Safety®	4252578-04	N/A			
Introcan Safety®	4252586-01	N/A			
Introcan Safety®	4252586-04	N/A			
Introcan Safety®	4252594-01	N/A			
Introcan Safety®	4252594-03	N/A			
Introcan Safety®	4252594-04	N/A			
Introcan Safety®-W	4253523-01	N/A			
Introcan Safety®-W	4253523-03	N/A			
Introcan Safety®-W	4253523-04	N/A			
Introcan Safety®-W	4253523JP	N/A			
Introcan Safety®-W	4253540-01	N/A			
Introcan Safety®-W	4253540-03	N/A			
Introcan Safety®-W	4253540-04	N/A			
Introcan Safety®-W	4253540JP	N/A			
Introcan Safety®-W	4253566-01	N/A			
Introcan Safety®-W	4253566-03	N/A			
Introcan Safety®-W	4253566-04	N/A			
Introcan Safety®-W	4253566JP	N/A			
Introcan Safety®-W	4253574-01	N/A			
Introcan Safety®-W	4253574-03	N/A			
Introcan Safety®-W	4253574-04	N/A			
Introcan Safety®-W	4253574JP	N/A			
Introcan Safety®-W	4253590-01	N/A			
Introcan Safety®-W	4253590-03	N/A			
Introcan Safety®-W	4253590-04	N/A			
Introcan Safety®-W	4253604-01	N/A			
Introcan Safety®-W	4253604-03	N/A			
Introcan Safety®-W	4253604-04	N/A			
Introcan Safety®-W	4253604JP	N/A			
Introcan Safety®-W	4253612-01	N/A			
Introcan Safety®-W	4253612-03	N/A			
Introcan Safety®-W	4253612-04	N/A			
Introcan Safety®-W	4253639-01	N/A			
Introcan Safety®-W	4253639-03	N/A			
Introcan Safety®-W	4253639JP	N/A			
Introcan Safety®-W	4253639-04	N/A			

Effective



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Introcan Safety®-W	4254503-01	N/A			
Introcan Safety®-W	4254503-03	N/A			
Introcan Safety®-W	4254503-04	N/A			
Introcan Safety®-W	4254511-01	N/A			
Introcan Safety®-W	4254511-03	N/A			
Introcan Safety®-W	4254511-04	N/A			
Introcan Safety®-W	4254538-01	N/A			
Introcan Safety®-W	4254538-03	N/A			
Introcan Safety®-W	4254538-04	N/A			
Introcan Safety®-W	4254546-01	N/A			
Introcan Safety®-W	4254546-03	N/A			
Introcan Safety®-W	4254554-01	N/A			
Introcan Safety®-W	4254554-03	N/A			
Introcan Safety®-W	4254554-04	N/A			
Introcan Safety®-W	4254562-01	N/A			
Introcan Safety®-W	4254562-03	N/A			
Introcan Safety®-W	4254562-04	N/A			
Introcan Safety®-W	4254570-01	N/A			
Introcan Safety®-W	4254570-03	N/A			
Introcan Safety®-W	4254570-04	N/A			
Introcan Safety®-W	4254597-01	N/A			
Introcan Safety®-W	4254597-03	N/A			
Introcan Safety®-W	4254597-04	N/A			
ProSet Intrapur®	4183913	N/A	40392390000008082P	class IIa	G1 012974 0607 Rev. 02 NB0123
ProSet Intrapur®	4183925	N/A			
ProSet Intrapur®	4183926	N/A			
ProSet Intrapur®	4183927	N/A			
ProSet Intrapur®	4183948	N/A			
ProSet Intrapur®	4183949	N/A			
ProSet Intrapur®	4184004	N/A			
ProSet Intrapur®	4184006	N/A			
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			





Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ProSet Intrapur®	4180351	N/A	403923900000075933	class IIa	G1 012974 0607 Rev. 02 NB0123
ProSet Intrapur®	4180350	N/A			
ProSet Discifix® C	4188960	N/A			
ProSet Discifix® C	4188959	N/A			
ProSet Discifix® C	4188957	N/A			
ProSet Discifix® C	4188105	N/A			
ProSet Discifix® C	4188071	N/A			
ProSet Discifix® C	4187954	N/A			
ProSet Discifix® C	4187826	N/A			
ProSet Discifix® C	4187202	N/A			
ProSet Discifix® C	4187199	N/A			
ProSet Discifix® C	4187032	N/A			
ProSet Discifix® C	4184963	N/A			
ProSet Discifix® C	4184491	N/A			
ProSet Discifix® C	4184246	N/A			
ProSet Discifix® C	4184030	N/A			
ProSet Discifix® C	4184022	N/A			
ProSet Discifix® C	4182635	N/A			
ProSet Discifix® C	4181234	N/A			
ProSet Discifix® C	4180965	N/A			
ProSet Discifix® C	4086481	N/A			
ProSet Discifix® C	4085230	N/A			
ProSet Discifix® C	4085213	N/A			
ProSet Discifix® C	4187203	N/A			
ProSet Discifix® C	4182308	N/A			
ProSet Discifix® C	4187527	N/A			
ProSet Discifix® C	4180437	N/A			
ProSet Discifix® C	4183088	N/A			
ProSet Discifix® C	4088698	N/A			
ProSet Discifix® C	4084792	N/A			
ProSet Discifix® C	4085300SF	N/A			
ProSet Discifix® C	4085086	N/A			
ProSet Discifix® C	4181027	N/A			
ProSet Discifix® C	4184005	N/A			
ProSet Discifix® C	4187291	N/A			
ProSet Discifix® C	4183312	N/A			
ProSet Discifix® C	4185366	N/A			
ProSet Discifix® C	4185927	N/A			
ProSet Discifix® C	4188188	N/A			
ProSet Discifix® C	4086482	N/A			
ProSet Discifix® C	4184327	N/A			
ProSet Discifix® C	4180439	N/A			

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Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ProSet Discifix® C	4180306	N/A			
ProSet Discifix® C	4182944	N/A			
ProSet Discifix® C	4083255	N/A			
ProSet Discifix® C	4187911	N/A			
ProSet Discifix® C	4187823	N/A			
ProSet Discifix® C	4187878	N/A			
ProSet Discifix® C	4085168	N/A			
ProSet Discifix® C	4189821	N/A			
ProSet Discifix® C	4188958	N/A			
ProSet Discifix® C	4187213	N/A			
ProSet Discifix® C	4187880	N/A			
ProSet Discifix® C	4083254	N/A			
ProSet Discifix® C	4189847	N/A			
ProSet Discifix® C	4188198	N/A			
ProSet Discifix® C	4183510	N/A			
ProSet Discifix® C	4187033	N/A			
ProSet Discifix® C	4188072	N/A			
ProSet Discifix® C	4183787	N/A			
ProSet Discifix® C	4180678	N/A			
ProSet Discifix® C	4180679	N/A			
ProSet Discifix® C	4187879	N/A			
ProSet Discifix® C	4185928	N/A			
ProSet Discifix® C	4086879	N/A			
ProSet Discifix® C	4188047	N/A			
ProSet Discifix® C	4189839	N/A			
ProSet Discifix® C	4183852	N/A			
ProSet Discifix® C	4185985	N/A			
ProSet Discifix® C	4085450SF	N/A			
ProSet Discifix® C	4089464	N/A			
ProSet Discifix® C	4182737	N/A			
ProSet Discifix® C	4180300	N/A			
ProSet Discifix® C	4183777	N/A			
ProSet Discifix® C	4185972	N/A			
ProSet Discifix® C	4184521	N/A			
ProSet Discifix® C	4182652	N/A			
ProSet Discifix® C	4184483	N/A			
ProSet Discifix® C	4087930	N/A			
ProSet Discifix® C	4184817	N/A			
ProSet Discifix® C	4187391	N/A			
ProSet Discifix® C	4182720	N/A			
ProSet Discifix® C	4185821N	N/A			
ProSet Discifix® C	4085434SF	N/A			

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Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ProSet Discifix® C	4188225	N/A			
ProSet Discifix® C	4186580	N/A			
ProSet Discifix® C	4186579	N/A			
ProSet Discifix® C	4085500SF	N/A			
ProSet Discifix® C	4181778	N/A			
ProSet Discifix® C	4180459	N/A			
ProSet Discifix® C	4188510	N/A			
ProSet Discifix® C	4180438	N/A			
ProSet Discifix® C	4086945	N/A			
ProSet Discifix® C	4187898	N/A			
ProSet Discifix® C	4185021	N/A			
ProSet Discifix® C	4187529	N/A			
ProSet Discifix® C	4088520	N/A			
ProSet Discifix® C	4181028	N/A			
ProSet Discifix® C	4182638	N/A			
ProSet Discifix® C	4088699	N/A			
ProSet Discifix® C	4180120	N/A			
ProSet Discifix® C	4180677	N/A			
ProSet Discifix® C	4182633	N/A			
ProSet Discifix® C	4182639	N/A			
ProSet Discifix® C	4187838	N/A			
ProSet Discifix® C	4084510	N/A			
ProSet Discifix® C	4182651	N/A			
ProSet Discifix® C	4187834	N/A			
ProSet Discifix® C	4180445	N/A			
ProSet Discifix® C	4083777	N/A			
ProSet Discifix® C	4187308	N/A			
ProSet Discifix® C	4184424	N/A			
ProSet Discifix® C	4182182	N/A			
Vasofix® Braunüle®	4268091B	N/A	40392390000007622Q	class IIa	G1 012974 0607 Rev. 02 NB0123
Vasofix® Braunüle®	4268113B	N/A			
Vasofix® Braunüle®	4268130B	N/A			
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			



Device Name	Article Number (under MDR application)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device(s)	Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Vasofix® Certo	4269217	N/A			
Vasofix® Certo	4269225	N/A			
Vasofix® Certo	4269330	N/A			
Extension Line	4051807	N/A	40392390000007893C	class IIa	G1 012974 0607 Rev. 02 NB0123
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			
ProSet Spiral Line	4090373	N/A			
ProSet Spiral Line	4090381	N/A			
ProSet Spiral Line	4090383	N/A			
ProSet Spiral Line	4090390	N/A			
ProSet Spiral Line	4090438	N/A			
ProSet Extension Line	4091621	N/A			
ProSet Extension Line	4091622	N/A			
ProSet Extension Line	4091660	N/A			
Vasofix® Safety	42680915-01	N/A	40392390000007642U	class IIa	G1 012974 0607 Rev. 02 NB0123
Vasofix® Safety	42680915-03	N/A			
Vasofix® Safety	42681135-01	N/A			
Vasofix® Safety	42681135-03	N/A			
Vasofix® Safety	42681305-01	N/A			
Vasofix® Safety	42681305-03	N/A			

Vasofix® Safety	42681565-01	N/A			
Vasofix® Safety	42681565-03	N/A			
Vasofix® Safety	42681725-01	N/A			
Vasofix® Safety	42681725-03	N/A			
Vasofix® Safety	42682105-01	N/A			
Vasofix® Safety	42682105-03	N/A			
Vasofix® Safety	42683345-01	N/A			
Vasofix® Safety	42683345-03	N/A			
Vasofix® Safety	42690715-01	N/A			
Vasofix® Safety	42690715-03	N/A			
Vasofix® Safety	42690715IN	N/A			
Vasofix® Safety	42690715-20	N/A			
Vasofix® Safety	42690985-01	N/A			
Vasofix® Safety	42690985-03	N/A			



Vasofix® Safety	4269098SIN	N/A			
Vasofix® Safety	4269098S-20	N/A			
Vasofix® Safety	4269110S-01	N/A			
Vasofix® Safety	4269110S-03	N/A			
Vasofix® Safety	4269110SIN	N/A			
Vasofix® Safety	4269110S-20	N/A			
Vasofix® Safety	4269136S-01	N/A			
Vasofix® Safety	4269136S-03	N/A			
Vasofix® Safety	4269136SIN	N/A			
Vasofix® Safety	4269136S-20	N/A			
Vasofix® Safety	4269152S-01	N/A			
Vasofix® Safety	4269152S-03	N/A			
Vasofix® Safety	4269152S-20	N/A			
Vasofix® Safety	4269179S-01	N/A			
Vasofix® Safety	4269179S-03	N/A			
Vasofix® Safety	4269179SIN	N/A			
Vasofix® Safety	4269179S-20	N/A			
Vasofix® Safety	4269217S-01	N/A			
Vasofix® Safety	4269217S-03	N/A			
Vasofix® Safety	4269217S-20	N/A			
Vasofix® Safety	4269225S-01	N/A			
Vasofix® Safety	4269225S-03	N/A			
Vasofix® Safety	4269225S-20	N/A			
Vasofix® Safety	4269330S-01	N/A			
Vasofix® Safety	4269330S-03	N/A			
Vasofix® Safety	4269330S-20	N/A			
ProSet Spiral Line	4091728	N/A	40392390000007893C	class IIa	G1 012974 0607 Rev. 02 NB0123
ProSet Spiral Line	4091736	N/A			
ProSet Spiral Line	4091740	N/A			
ProSet Spiral Line	4091752	N/A			
ProSet Spiral Line	4092539	N/A			
ProSet Spiral Line	4092937	N/A			
ProSet Spiral Line	4092945	N/A			
ProSet Spiral Line	4092953	N/A			
ProSet Spiral Line	4092961	N/A			
ProSet Spiral Line	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			

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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			
ProSet Extension Line	4095251	N/A			
ProSet Extension Line	4097531	N/A			
Extension Line	4097572	N/A			
ProSet Spiral Line	4099362	N/A			
ProSet Extension Line	4185841	N/A			
ProSet Extension Line	4185842	N/A			
ProSet Spiral Line	4187466	N/A			
ProSet Spiral Line	4187467	N/A			
ProSet Spiral Line	4187468	N/A			
ProSet Spiral Line	4187469	N/A			
ProSet Spiral Line	4188080	N/A			
Extension Line	9500049	N/A			
Extension Line	9500057	N/A			
Extension Line	9500065	N/A			
Infusomat®plus Line SafeSet	8700390	N/A	40392390000014782X	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat®plus Line SafeSet	8700391	N/A			
Infusomat®plus Line SafeSet	8700392	N/A	403923900000259235	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space Line SafeSet	8700140SP	N/A	40392390000014772V	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space Line SafeSet	8700141SP	N/A			
Infusomat® Space Line SafeSet	8700142SP	N/A	403923900000259133	class IIa	G1 012974 0607 Rev. 02 NB0123
Intrafix® Primeline	4060369L	N/A	40392390000007812U	class IIa	G1 012974 0607 Rev. 02 NB0123
Intrafix® Primeline	4060407	N/A			
Intrafix® Primeline	4062158	N/A			
Intrafix® Primeline	4062158C	N/A			
Intrafix® Primeline	4062182	N/A			
Intrafix® Air	4062955	N/A			
Intrafix® Primeline	4062957E	N/A			
Intrafix® Primeline	4062981L	N/A			
Intrafix® Primeline	4062982L	N/A			
Intrafix® Primeline	4062983L	N/A			
Intrafix® SafeSet	4063000	N/A			
Intrafix® SafeSet	4063001	N/A			
Intrafix® SafeSet	4063003	N/A			
Intrafix® SafeSet	4063004	N/A			
Intrafix® SafeSet	4063004C	N/A			
Intrafix® SafeSet	4063004M	N/A			
Intrafix® SafeSet	4063005	N/A			
Intrafix® SafeSet	4063006	N/A			
Drainobag® Basse Pression	5524237	N/A	403923900000281736	class IIa	G1 012974 0607 Rev. 02
Drainobag® Lock 300	5522390	N/A			



Drainobag® 150	5523753	N/A			NB0123
Drainobag® Lock 150	5523761	N/A			
Drainobag® Lock 150	55237611	N/A			
Drainobag® Lock 400	5523602	U2000600			
Drainobag® 600 V	5523605	N/A	40392390000007973B	class IIa	G1 012974 0607 Rev. 02 NB0123
Drainobag® Lock 600 V	5523648	N/A			
Drainobag® Lock 600 V	5523649	N/A			
Drainobag® Basse Pression TL	5524210	N/A			
Drainobag® 300 V	5522322	N/A			
Drainobag® Lock 300 V	5522340	N/A			
Drainobag® Lock 300 V	55223401	N/A			
Drainobag® 150 V	5523702	N/A			
Drainobag® 150 VL	5523710	N/A			
Drainobag® Lock 150 V	5523729	N/A			
Drainobag® Lock 150 VL	5523737	N/A			
Drainobag® Lock 150 VL	55237371	N/A			
Drainobag® 400 V	5523601	U2000500			
Drainobag® Lock 400 V	5523603	U2000700			
Drainobag® Lock 600 K 10	5523400	N/A	40392390000028193A	class IIa	G1 012974 0607 Rev. 02 NB0123
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	N/A	40392390000007812U	class IIa	G1 012974 0607 Rev. 02 NB0123
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			
ProSet Intrafix® Primeline	4182111	N/A			
ProSet Intrafix® SafeSet	4182179	N/A			
ProSet Intrafix® SafeSet	4182409	N/A			
ProSet Intrafix® SafeSet	4183450	N/A			
ProSet Intrafix® SafeSet	4183455	N/A			
ProSet Intrafix® SafeSet	4183665	N/A			
ProSet Intrafix® Primeline	4183791	N/A			
ProSet Intrafix® SafeSet	4184321	N/A			
ProSet Intrafix® SafeSet	4186097	N/A			
ProSet Intrafix® SafeSet	4186109	N/A			
ProSet Intrafix® SafeSet	4186110	N/A			
ProSet Intrafix® Primeline	4186168	N/A			
ProSet Intrafix® Primeline	4186320	N/A			
ProSet Intrafix® Primeline	4186711	N/A			
ProSet Intrafix® Primeline	4186950	N/A			
ProSet Intrafix® SafeSet	4186980	N/A			
ProSet Intrafix® SafeSet	4186981	N/A			

Effective



ProSet Intrafix® Primeline	4187005	N/A			
ProSet Intrafix® SafeSet	4187006	N/A			
ProSet Intrafix® Primeline	4187007	N/A			
ProSet Intrafix® Primeline	4187008	N/A			
ProSet Intrafix® SafeSet	4187009	N/A			
ProSet Intrafix® Primeline	4187010	N/A			
ProSet Intrafix® SafeSet	4187011	N/A			
ProSet Intrafix® SafeSet	4187113	N/A			
ProSet Intrafix® Primeline	4187172	N/A			
ProSet Intrafix®	4187176	N/A			
ProSet Intrafix® Primeline	4187334	N/A			
ProSet Intrafix® Primeline	4187555	N/A			
ProSet Intrafix® Primeline	4187946	N/A			
ProSet Intrafix® SafeSet	4187989	N/A			
ProSet Intrafix® Primeline	4188020	N/A			
ProSet Intrafix® SafeSet	4188030	N/A			
ProSet Intrafix® SafeSet	4188110	N/A			
ProSet Intrafix® SafeSet	4188113	N/A			
ProSet Intrafix® SafeSet	4188114	N/A			
ProSet Intrafix® SafeSet	4188115	N/A			
ProSet Intrafix® SafeSet	4188116	N/A			
ProSet Intrafix® SafeSet	4188117	N/A			
ProSet Intrafix® Primeline	4187105	N/A			
ProSet Intrafix® SafeSet	4188120	N/A			
ProSet Intrafix® SafeSet	4188136	N/A			
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	N/A			G2S 012974 0457 Rev. 02 NB0123
Intrafix® Primeline	4062877	N/A	40392390000014832Q	class IIa	G1 012974 0607 Rev. 02 NB0123
Intrafix® SafeSet	4062878	N/A			
Intrafix® Primeline	4110001	N/A			
Intrafix® Primeline	4110002	N/A			
ProSet Intrafix®	4186914	N/A			
Intrafix® Primeline	4060563	N/A	40392390000014822N	class IIa	G1 012974 0607 Rev. 02 NB0123
SafeSet	4063000A	N/A	40392390000007822W	class IIa	G1 012974 0607 Rev. 02 NB0123
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	N/A	40392390000008622V	class IIa	G1 012974 0607 Rev. 02 NB0123
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			
Infusomat® Plus Line SafeSet	8700220	N/A			
Infusomat® Plus Line	8700330	N/A			
Infusomat® Plus Line	8700320	N/A			
ProSet Original Perfusor® Line	4092930	N/A	40392390000014802J	class IIa	G1 012974 0607 Rev. 02 NB0123
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			
ProSet Original Perfusor® Line	4183933	N/A			
ProSet Original Perfusor® Line	4183935	N/A			
ProSet Original Perfusor® Line	4183936	N/A			
Infusomat® Plus Line	8700350CN	N/A	403923900000086533	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Plus Line	8700350-20	N/A			
Infusomat® Plus Line	8700360	N/A			
Infusomat® Space Line	8700132SP	N/A	40392390000008693B	class IIa	G1 012974 0607 Rev. 02 NB0123
Infusomat® Space Line	8270074SP	N/A	403923900000086635	class IIa	G1 012974 0607 Rev. 02 NB0123
ProSet Infusomat® Space Line	8250908SP	N/A			
ProSet Infusomat® Space Line	8250902SP	N/A			
ProSet Infusomat® Space Line	8250900SP	N/A			
ProSet Infusomat® Space Line	8250077SP	N/A			
ProSet Infusomat® Space Line	4182586SP	N/A			
ProSet Infusomat® Space Line	4181557SP	N/A			
ProSet Infusomat® Space Line	8250958SP	N/A			
Infusomat® Plus Line	8700370CN	N/A	40392390000008632X	class IIa	G1 012974 0607 Rev. 02
Infusomat® Plus Line	8700400	N/A			



Infusomat® Plus Line	8700370	N/A	4039239000001006ZF	class IIa	NB0123
Omnican® fine	9167641WE	N/A			G1 012974 0607
Omnican® fine	9167650WE	N/A			Rev. 02
					NB0123
Omnican® fine	9167684WE	N/A			
Omnican® fine	9167820WE	N/A			
Omnican® fine	929G12S-03	N/A			
Omnican® fine	929G12S-41	N/A			
Omnican® fine	929G12S-43	N/A			
Omnican® fine	931G04S-03	N/A			
Omnican® fine	931G04S-41	N/A			
Omnican® fine	931G04S-43	N/A			
Omnican® fine	931G04SCN	N/A			
Omnican® fine	931G04SCN1	N/A			
Omnican® fine	931G06S-03	N/A			
Omnican® fine	931G06S-41	N/A			
Omnican® fine	931G06S-43	N/A			
Omnican® fine	931G06S-AP	N/A			
Omnican® fine	931G06SCN	N/A			
Omnican® fine	931G06SCN1	N/A			
Omnican® fine	931G08S-03	N/A			
Omnican® fine	931G08S-41	N/A			
Omnican® fine	931G08S-43	N/A			
Omnican® fine	931G08S-44	N/A			
Omnican® fine	932G04S-03	N/A			
Omnican® fine	932G04S-41	N/A			
Omnican® fine	932G04S-43	N/A			
Omnican® fine	932G04S-AP	N/A			
Omnican® fine	932G04SCN	N/A			
Omnican® fine	932G04SCN1	N/A			
Omnican® fine	932G05SCN	N/A			
Omnican® fine	932G05SCN1	N/A			
Omnican® fine	932G06S-03	N/A			
Omnican® fine	932G06S-41	N/A			
Omnican® fine	932G06S-43	N/A			
Omnican® fine	932G06SCN	N/A			
Omnican® fine	932G06SCN1	N/A			
Omnican® fine	932P04	N/A			
Omnican® fine	932P05	N/A			
Omnican® fine	932P06	N/A			
Infusomat® Plus Line SafeSet	8700270	N/A	40392390000020742A	class IIa	G1 012974 0607
Infusomat® Plus Line SafeSet	8700260-20	N/A			Rev. 02
Infusomat® Plus Line SafeSet	8700260	N/A			NB0123
Original Perfusor® Line	8722865	N/A	40392390000008722Y	class IIa	G1 012974 0607
					Rev. 02
					NB0123
Infusomat® Plus Line	8700410	N/A	40392390000008642Z	class IIa	G1 012974 0607
					Rev. 02
					NB0123
ProSet Infusomat® Space Line	4182190SP	N/A	403923900000086737	class IIa	G1 012974 0607
ProSet Infusomat® Space Line	4180639SP	N/A			Rev. 02



ProSet Infusomat® Space Line	4180020SP	N/A			NB0123
ProSet Infusomat® Space Line	8250918SP	N/A			
ProSet Infusomat® Space Line	8251001SP	N/A			
ProSet Infusomat® Space Line	8251002SP	N/A			
ProSet Infusomat® Space Line	4182191SP	N/A			
ProSet Infusomat® Space Line	4183900	N/A			
ProSet Infusomat® Space Line	8270058SP	N/A			
ProSet Infusomat® Space Line	8252658SP	N/A			
ProSet Infusomat® Space Line	8250358SP	N/A			
ProSet Infusomat® Space Line	8250903SP	N/A			
ProSet Infusomat® Space Line	4182653SP	N/A			
ProSet Infusomat® Space Line	4187897	N/A			
ProSet Infusomat® Space Line	4184904SP	N/A			
ProSet Infusomat® Space Line	4188063SP	N/A			
ProSet Infusomat® Space Line	4180635SP	N/A			
ProSet Infusomat® Space Line	4188166SP	N/A			
ProSet Infusomat® Space Line	4189980SP	N/A			
ProSet Infusomat® Space Line	4186524SP	N/A			
ProSet Infusomat® Space Line	4189979SP	N/A			
ProSet Infusomat® Space Line	4089340SP	N/A			
ProSet Infusomat® Space Line	8250905SP	N/A			
ProSet Infusomat® Space Line	4183911	N/A			
ProSet Infusomat® Space Line	4185489	N/A			
ProSet Infusomat® Space Line	4187769SP	N/A			
ProSet Infusomat® Space Line	8251284SP	N/A			
ProSet Infusomat® Space Line	4185308SP	N/A			
ProSet Infusomat® Space Line	8250904SP	N/A			
ProSet Infusomat® Space Line	4186486SP	N/A			
Infusomat® Space Line	8700095SP	N/A			
Infusomat® Space Line	8700110SP	N/A			
Infusomat® Space Line	8270350SP	N/A			
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			
ProSet Infusomat® Space Line	4185976SP	N/A			
ProSet Infusomat® Space Line	4181558SP	N/A			
ProSet Infusomat® Space Line	4089391SP	N/A			
ProSet Infusomat® Space Line	8270597SP	N/A			

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Infusomat® Space Line SafeSet	8270358SP	N/A			
ProSet Infusomat® Space Line	4187899	N/A			
ProSet Infusomat® Space Line	4183189SP	N/A			
ProSet Infusomat® Space Line	4186940SP	N/A			
Infusomat® Space Line	8700087SP-26	N/A			
Infusomat® Space Line	8700087SP-01	N/A			
ProSet Infusomat® Space Line	8251005SP	N/A			
ProSet Infusomat® Space Line	8251004SP	N/A			
ProSet Infusomat® Space Line	8251003SP	N/A			
ProSet Infusomat® Space Line	4183950SP	N/A			
ProSet Infusomat® Space Line	4180631SP	N/A			
ProSet Infusomat® Space Line	4183901	N/A			
ProSet Infusomat® Space Line	4189981SP	N/A			
ProSet Infusomat® Space Line	4187377	N/A			
ProSet Infusomat® Space Line	4182189SP	N/A			
ProSet Infusomat® Space Line	8252659SP	N/A			
ProSet Original Perfusor® Line	4185687	N/A	40392390000008712W	class IIa	G1 012974 0607 Rev. 02 NB0123
ProSet Original Perfusor® Line	4085129	N/A			
ProSet Original Perfusor® Line	8250803	N/A			
ProSet Original Perfusor® Line	4183971	N/A			
ProSet Original Perfusor® Line	4183970	N/A			
Original Perfusor® Line	8255504N	N/A			
Original Perfusor® Line	8745919N	N/A			
Original Perfusor® Line	8722940	N/A			
Original Perfusor® Line	8723060CN	N/A			
Original Perfusor® Line	8255253	N/A			
Original Perfusor® Line	8723024	N/A			
Original Perfusor® Line	8723023	N/A			
Original Perfusor® Line	8723026	N/A			
Original Perfusor® Line	8723025	N/A			
Original Perfusor® Line	8723021	N/A			
Original Perfusor® Line	8723020	N/A			
ProSet Original Perfusor® Line	8250782	N/A			
ProSet Original Perfusor® Line	8250847	N/A			
Original Perfusor® Line	8722941	N/A			
Original Perfusor® Line	8722960	N/A			
Original Perfusor® Line	8250146	N/A			
Original Perfusor® Line	8723060	N/A			
ProSet Original Perfusor® Line	4185595	N/A			
Original Perfusor® Line	8272565	N/A			
Original Perfusor® Line	8255067	N/A			
Original Perfusor® Line	8722960-20	N/A			
Original Perfusor® Line	8255504NCN	N/A			
Original Perfusor® Line	8722862-20	N/A			
Original Perfusor® Line	8723060-20	N/A			
Original Perfusor® Line	8722862	N/A			
Original Perfusor® Line	8722935	N/A			
Original Perfusor® Line	8255172	N/A			
Original Perfusor® Line	8255059	N/A			
ProSet Original Perfusor® Line	4092933	N/A			

Effective



ProSet Original Perfusor® Line	4092932	N/A			
ProSet Original Perfusor® Line	4092931	N/A			
Original Perfusor® Line	8722935CN	N/A			
Original Perfusor® Line	8722870N	N/A			
Original Perfusor® Line	8722820	N/A			
Original Perfusor® Line	8722935-20	N/A			
Original Perfusor® Line	8255490	N/A			
ProSet Original Perfusor® Line	4183969	N/A			
Original Perfusor® Line	0066088K	N/A			
Original Perfusor® Line	0066086H	N/A			
ProSet Original Perfusor® Line	4180441	N/A			
Original Perfusor® Line	0066087J	N/A			
Original Perfusor® Line	0009483H	N/A			
ProSet Infusomat® Space Line	4186850	N/A	40392390000014792Z	class IIa	G1 012974 0607 Rev. 02 NB0123
ProSet Infusomat® Space Line	4186842SP	N/A			
Infusomat® Space Line SafeSet	8700128SP	N/A			
Infusomat® Space Line	8700127SP	N/A			
Infusomat® Space Line	8250437SP	N/A			
Infusomat® Space Line SafeSet	8250438SP	N/A			
ProSet Infusomat® Space Line	8252671SP	N/A			
Sangofix®	4050192	N/A	40392390000027342Z	class IIa	G1 012974 0607 Rev. 02 NB0123
Sangofix®	4050192H	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	N/A	40392390000000392P	class IIa	G1 012974 0607 Rev. 02 NB0123
Sangofix® Air	4050151	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 Perfusor® Line	8723001	N/A	40392390000027242W	class IIa	G1 012974 0607 Rev. 02 NB0123
Infuvalve®	4094000N	N/A	40392390000008102A	class IIa	G1 012974 0607 Rev. 02 NB0123
Combi-Stopper	4495209	N/A	40392390000008112C	class IIa	G1 012974 0607 Rev. 02 NB0123
Combi-Stopper	4495101R	N/A			
Safeflow Extension Set	4097154N	N/A	40392390000008152L	class IIa	G1 012974 0607 Rev. 02 NB0123
Safeflow Extension Set	4097145N	N/A			
Safeflow Extension Set	4097154	N/A			



Safeflow	409110H	N/A	40392390000008162N	class IIa	G1 012974 0607 Rev. 02 NB0123
Safeflow	409100CN	N/A			
Safeflow	409101H	N/A			
Safeflow	409100H	N/A			
Safeflow Extension Set	4097148N	N/A	40392390000027222S	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnican® fine	931A04E	N/A	4039239000001008ZK	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnican® 50	9151117S	N/A	40392390000009362Z	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnican® 50	9151125S	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	N/A	403923900000093937	class IIa	G1 012974 0607 Rev. 02 NB0123
IBSA FSH/LH	9161530S	N/A			
Serofine™ needle	16441MS	N/A	4039239000001007ZH	class IIa	G1 012974 0607 Rev. 02 NB0123
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	N/A			
Pen Needle B. Braun F-Pen DS	P1400075	N/A			
Serofine® needle	16443EMD	N/A			
Drainobag® Lock 600 K 14	5523443	N/A	40392390000028193A	class IIa	G1 012974 0607 Rev. 02 NB0123
Drainobag® Lock 600 K 14	5523444	N/A			
Drainobag® Lock 600 K 16	5523460	N/A			
Drainobag® Lock 600 K 16	5523461	N/A			
Drainobag® 150 K 6	5523800	N/A			
Drainobag® 150 K 6	55238001	N/A			
Drainobag® 150 K 8	5523850	N/A			
Drainobag® 150 K 8	55238501	N/A			
Omnifix® 40 Duo	9161333V	N/A	4039239000001217ZW	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnifix® 100 Duo	9161376C	N/A			
Omnifix® 100 Duo	9161376V	N/A			
Omnifix® Luer Duo	4643011C	N/A	403923900000077633	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnifix® Luer Duo	4643100V	N/A			
Omnifix® Luer Duo	4643102C	N/A			
Omnifix® Luer Duo	4643102V	N/A			
Omnifix® Luer Duo	4643105V	N/A			

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

Freigabe bestätigt: Dokument Richtig zugeordnet / vollständig und lesbar

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Omnifix® Luer Duo	4643119C	N/A			
Omnifix® Luer Duo	4643119V	N/A			
Omnifix® Luer Duo	4643127C	N/A			
Omnifix® Luer Duo	4643127V	N/A			
Omnifix® Luer Duo	4643135C	N/A			
Omnifix® Luer Duo	4643135V	N/A			
Omnifix®-F Luer Duo	9161465V	N/A			
Omnifix® Luer Duo	4643161	N/A			
Omnifix® Luer Lock Solo	4617022V	N/A	403923900000077735	class IIa	G1 012974 0607 Rev. 02 NB0123
Omnifix® Luer Lock Solo	4617022V-03	N/A			
Omnifix® Luer Lock Solo	4617029V	N/A			
Omnifix® Luer Lock Solo	4617053V	N/A			
Omnifix® Luer Lock Solo	4617053V-03	N/A			
Omnifix® Luer Lock Solo	4617100CA	N/A			
Omnifix® Luer Lock Solo	4617100V	N/A			
Omnifix® Luer Lock Solo	4617100V-03	N/A			
Omnifix® Luer Lock Solo	4617207V	N/A			
Omnifix® Luer Lock Solo	4617207V-03	N/A			
Omnifix® Luer Lock Solo	4617304F	N/A			
Omnifix® Luer Lock Solo	4617509F	N/A			
Omnifix® Luer Lock Solo	4617509F-03	N/A			
Omnifix® Luer Lock Solo	4617510F-06	N/A	4039239000000207022	class IIa	G1 012974 0607 Rev. 02 NB0123
Sterican® Safety Needle	4670002S-01	N/A	403923900000076936	class IIa	G1 012974 0607 Rev. 02 NB0123
Sterican® Safety Needle	4670005S-01	N/A			
Sterican® Safety Needle	4670008S-01	N/A			
Sterican® Safety Needle	4670008SBR	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			
Sterican® Safety Needle	4670052S-01	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	403923900000076834	class IIa	G1 012974 0607 Rev. 02 NB0123
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®	4660021	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®	4665600	N/A			
Sterican®	4665635	N/A			
Sterican®	4665643	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	N/A	40392390000007742X	class IIa	G1 012974 0607 Rev. 02 NB0123
Injekt® Luer Duo	4645022C	N/A	40392390000007752Z	class IIa	G1 012974 0607 Rev. 02 NB0123
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	N/A			
Injekt® Luer Duo	4645200UA	N/A			

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Injekt® Luer Duo	4645200V	N/A	403923900000076936	class IIa	G1 012974 0607 Rev. 02 NB0123
Injekt® Luer Duo	4647220	N/A			
Injekt®-F Luer Duo	9166033V	N/A			
Sterican® Safety Needle	4670030SBR	N/A			
Sterican® Safety Needle	4670053SBR	N/A			
Contiplex® D	4898323	N/A	40392390000008522S	class IIa	G1 012974 0607 Rev. 02 NB0123
Contiplex® D	4898325	N/A			
Contiplex® D	4898305	N/A			
Contiplex® D	4898308	N/A			
Contiplex® D	4898311	N/A			
Contiplex® D	4898335	N/A			
Contiplex® D NRFit®	4898305NR	N/A			
Contiplex® D NRFit®	4898335NR	N/A			
Contiplex® D NRFit®	4898311NR	N/A			
Contiplex® D NRFit®	4898323NR	N/A			
Contiplex® D NRFit®	4898325NR	N/A			
Contiplex® D	4895819NCN	N/A			
Contiplex® D	4894235NCN	N/A			
Contiplex® D	4894391NCN	N/A			
Contiplex® D	4898205	N/A	40392390000008532U	class IIa	G1 012974 0607 Rev. 02 NB0123
Contiplex® D	4898211	N/A			
Contiplex® D	4898235	N/A			
Contiplex® C	4898115	N/A	403923900000085632	class IIa	G1 012974 0607 Rev. 02 NB0123
Contiplex® C	4898130	N/A			
Contiplex® C NRFit®	4898115NR	N/A			
Contiplex® C NRFit®	4898130NR	N/A			
Ultraplex® 360	4892603-01	N/A	40392390000008552Y	class IIa	G1 012974 0607 Rev. 02 NB0123
Ultraplex® 360	4892603CN	N/A			
Ultraplex® 360 NRFit®	4892603NR-01	N/A			
Ultraplex® 360	4892605-01	N/A			
Ultraplex® 360	4892605CN	N/A			
Ultraplex® 360 NRFit®	4892605NR-01	N/A			
Ultraplex® 360	4892608-01	N/A			
Ultraplex® 360	4892608CN	N/A			
Ultraplex® 360 NRFit®	4892608NR-01	N/A			
Ultraplex® 360	4892610-01	N/A			
Ultraplex® 360	4892610CN	N/A			
Ultraplex® 360 NRFit®	4892610NR-01	N/A			
Ultraplex® 360	4892615-01	N/A			
Ultraplex® 360	4892615CN	N/A			
Ultraplex® 360 NRFit®	4892615NR-01	N/A			
Stimuplex® D	4892105	N/A	40392390000008502N	class IIa	G1 012974 0607 Rev. 02 NB0123
Stimuplex® D	4892105-23	N/A			
Stimuplex® D	4892105CN	N/A			
Stimuplex® D NRFit®	4892105NR	N/A			
Stimuplex® D	4892108	N/A			
Stimuplex® D	4892108-23	N/A			
Stimuplex® D	4892108CN	N/A			
Stimuplex® D NRFit®	4892108NR	N/A			

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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	N/A	40392390000008512Q	class IIa	G1 012974 0607 Rev. 02 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			
Stimuplex® Ultra 360®	4892510-20	N/A			
Stimuplex® 360®	4892510CN	N/A			
Stimuplex® Ultra 360® NRFit®	4892510NR-01	N/A			
Stimuplex® Ultra 360®	4892515-01	N/A			

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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	N/A			
Omnifix® Lock	4617014	N/A			
Omnifix® Lock	4617021	N/A			
Omnifix® Lock	4617508F-01	N/A			
Original Perfusor® Syringe 20 ml	8728615	N/A	403923900000044ZG	class IIa	G1 012974 0607 Rev. 02 NB0123
Original Perfusor® Syringe 20 ml	8728615C	N/A	403923900000077939	class IIa	G1 012974 0607 Rev. 02 NB0123
Original Perfusor® Syringe 20 ml	8728623	N/A			
Original Perfusor® Syringe 20 ml	8728623C	N/A			
Original Perfusor® Syringe 50 ml	8728810F-04	N/A	40392390000029923R	class IIa	G1 012974 0607 Rev. 02 NB0123
Original Perfusor® Syringe 50 ml	8728810F-06	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	403923900000077939	class IIa	G1 012974 0607 Rev. 02 NB0123
Original Perfusor® Syringe 50 ml	8728844F-20	N/A			
Original Perfusor® Syringe 50 ml	8728852F-04	N/A			
Original Perfusor® Syringe 50 ml	8728852F-06	N/A	40392390000029923R	class IIa	G1 012974 0607 Rev. 02 NB0123
Original Perfusor® Syringe 50 ml	8728852F-20	N/A			
Original Perfusor® Syringe 50 ml	8728861F-04	N/A			
Original Perfusor® Syringe 50 ml	8728861F-06	N/A	403923900000207124	class IIa	G1 012974 0607 Rev. 02 NB0123
Original Perfusor® Syringe 50 ml	8728861F-20	N/A			
Original Perfusor® Syringe 50 ml	8728845F-01	N/A	40392390000007802S	class IIa	G1 012974 0607 Rev. 02 NB0123
Cystofix®	4450100	N/A			
Cystofix®	4450120	N/A			
Cystofix®	4450130	N/A			
Cystofix®	4450150	N/A	40392390000009993R	class IIa	G1 012974 0607 Rev. 02 NB0123
Cystofix®	4450160	N/A			
Cystofix®	4450170	N/A			
Cystofix®	4450180	N/A			
Cystofix®	4450200	N/A			
Cystofix®	4450220	N/A	403923900000100023	class IIb	G1 012974 0607 Rev. 02 NB0123
Cystofix SG	4450410	N/A			
Cystofix SG	4450412	N/A			
Cystofix SG	4450414	N/A			
		N/A			
Cystofix SG	4450416		403923900000100227	class IIb	G1 022239 0080 Rev. 03 NB0123 B.BRAUN MEDICAL SAS***
Cystofix	4450010	N/A			
Cystofix	4450012	N/A			
Cystofix	4450014	N/A			
Cystofix	4450016	N/A			
Cystofix	4450512	N/A			
Cystofix	4450514	N/A	403923900000100125	class IIb	G1 022239 0080 Rev. 03 NB0123 B.BRAUN MEDICAL SAS***





Cystofix	4450516	N/A			
Cystofix	4450712	N/A			
Cystofix	4450714	N/A			
Cystofix	4450716	N/A			
Cystofix	4450718	N/A			
Cystofix	4450720	N/A			
Vasco® OP Powdered	6031510	N/A			G1 012974 0607
Vasco® OP Powdered	6031525	N/A			Rev. 02
Vasco® OP Powdered	6031532	N/A			NB0123
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			
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 Free	9208291	N/A			
Vasco® OP Free	9208305	N/A			
Vasco® OP Free	9208313	N/A			
Vasco® OP Free	9208321	N/A			
Vasco® OP Free	9208330	N/A			
Vasco® OP Free	9208348	N/A			

class IIa

4039239000009272Y

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Vasco® OP Free	9208356	N/A			
Vasco® OP Free	9208364	N/A			

** the MDD certificate was originally issued to the company 'B. Braun Avitum Italy S.p.A' which is part of the larger organization B. Braun Group. Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.

*** the MDD certificate was originally issued to the company 'B. Braun Medical SAS' which is part of the larger organization B. Braun Group. Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/04/23	713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	Initial issue
2024/05/22	713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	Second Issue (Revision 1): Editorial corrections in several product names (e.g., missing trademark sign). Adding missing article codes, deleting obsolete article numbers, correction of BUDI.
2024//06/22	713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	Third Issue (Revision 2): Editorial corrections of wrongly deleted article number in rev. 01931A04E. Adding missing article code 497429 for NaCl 0.9 % solution d'irrigation (Ecolav 30 ml) under BUDI 40392390000025022A. Correction of layout of table.

Effective

TÜV SÜD Product Service GmbH

Lettera di conferma

CL 012974 0657 Rev. 00

Riferimento: 713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 /
713316916 / 713316919 / 713316912

Per chi è coinvolto,

Conferma dello status di domanda formale, accordo scritto e sorveglianza adeguata nel quadro del Regolamento UE 2023/607 che modifica il Regolamento (UE) 2017/745 (di seguito MDR) per quanto riguarda le disposizioni transitorie per determinati dispositivi medici e dispositivi medico-diagnostici in vitro.

Con la presente TÜV SÜD Product Service GmbH, designata ai sensi dell'MDR e identificata con il numero 0123 su NANDO, conferma di aver ricevuto una richiesta formale ai sensi della Sezione 4.3, primo comma dell'Allegato VII dell'MDR e di aver firmato un accordo scritto in conformità con la sezione 4.3, secondo comma dell'allegato VII dell'MDR con il produttore sopra indicato con quanto segue

Numero SRN: DE-MF-000000201

I dispositivi oggetto della domanda formale e dell'accordo scritto sopra menzionati sono individuati nelle Tabelle seguenti.

- La tabella 1 identifica i dispositivi per i quali è stata ricevuta una richiesta MDR, concluso un accordo scritto e per i quali TÜV SÜD Product Service GmbH è anche responsabile della sorveglianza adeguata dei dispositivi corrispondenti ai sensi della Direttiva applicabile.

Di seguito sono riportate le tempistiche di transizione ai sensi dell'articolo 120, paragrafo 3, dell'MDR che si applicano ai dispositivi oggetto della presente lettera, a condizione che il produttore continui a rispettare le altre condizioni specificate nell'articolo 120, paragrafo 3 quater, dell'MDR:

- 26 maggio 2026 per i dispositivi impiantabili su misura di Classe III
- 31 dicembre 2027 per i dispositivi di Classe III e i dispositivi impiantabili di Classe IIb (eccetto suture, graffette, otturazioni dentali, apparecchi ortodontici, corone dentali, viti, cunei, placche, fili, perni, clip e connettori)
- 31 dicembre 2028 per gli altri dispositivi di Classe IIb, Classe IIa, Classe I immessi sul mercato in condizioni sterili, con funzione di misurazione.
- 31 dicembre 2028 per i dispositivi che non richiedono il coinvolgimento di un organismo notificato ai sensi della MDD ma lo richiedono ai sensi dell'MDR (ad esempio, dispositivi di classe I che si qualificano come strumenti chirurgici riutilizzabili)

Ci riserviamo il diritto di fatturare qualsiasi emissione, copia, modifica e/o variazione della lettera di conferma secondo impegno.

Per la validità della lettera di conferma vedere www.tuvsud.com/ps-cert?q=cert:CL 012974 0657 Rev. 00

In caso di domande, contattare medical_devices@tuvsud.com.

A nome dell'organismo notificato TÜV SÜD Product Service GmbH,

23 aprile 2024.

Tabella 1: Dispositivi oggetto della presente lettera e per i quali TÜV SÜD Product Service GmbH è anche responsabile della sorveglianza adeguata dei dispositivi corrispondenti ai sensi della Direttiva applicabile:

Nome del dispositivo	Numero articolo (sotto la domanda MDR)	Se il dispositivo MDR è un dispositivo sostitutivo, identificazione del/i dispositivo/i MDD/AIMDD corrispondente/i	BASIC UDI-DI (sotto la domanda MDR)	Classificazione del dispositivo MDR (come proposto dal produttore e verificato durante la revisione dell'applicazione) Classe Im: dispositivi di Classe I con funzione di misurazione La classe è: dispositivi di classe I in condizioni sterili	Riferimenti del certificato MDD/AIMDD dei dispositivi soggetti all'applicazione MDR e identificazione dell'NB

Per la lista fare riferimento alla dichiarazione originale, pagine da 3 a 42

** il certificato MDD è stato originariamente rilasciato alla società “B. Braun Avitum Italy S.p.A’ che fa parte dell’organizzazione più ampia B. Braun Group. Pertanto, vengono concesse ulteriori disposizioni transitorie sulla base delle domande e risposte della Commissione UE sugli aspetti pratici relativi all’attuazione del Regolamento (UE) 2023/607 (luglio 2023), sezione 9.2.

***il certificato MDD è stato originariamente rilasciato alla società “B. Braun Medical SAS’ che fa parte dell’organizzazione più ampia B. Braun Group. Pertanto, vengono concesse ulteriori disposizioni transitorie sulla base delle domande e risposte della Commissione UE sugli aspetti pratici relativi all’attuazione del Regolamento (UE) 2023/607 (luglio 2023), sezione 9.2.

Tabella 2: Dispositivi oggetto della presente lettera e per i quali TÜV SÜD Product Service GmbH NON è responsabile della sorveglianza adeguata dei dispositivi corrispondenti ai sensi della Direttiva applicabile: NON APPLICABILE

Cronologia delle versioni della lettera di conferma

Data	Riferimento interno di TÜV SÜD Product Service GmbH riconducibile ad ogni versione della lettera	Azione
2024/04/23	713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	Emissione iniziale
2024/05/22	713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	Seconda edizione(revisione 1): correzioni editoriali in diversi nomi di prodotti (ad es. segno di marchio mancante). Aggiunta codici articolo mancanti, eliminazione codici articolo obsoleti, correzione BUDI.
2024//06/22	713257209 / 713279371 / 713313043 / 713316921 / 713316928 / 713316930 / 713316916 / 713316919 / 713316912	Terza edizione (Revisione 2): Correzioni editoriali del numero di articolo erroneamente cancellato nella rev. 01931A04E. Aggiunto il codice articolo mancante 497429 per la soluzione d'irrigazione NaCl 0,9% (Ecolav 30 ml) sotto BUDI 40392390000025022A. Correzione del layout della tabella.