



**Add value.
Inspire trust.**

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

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

| Your reference/letter of | Our reference/name | Tel. extension/Email | Fax extension | Date | Page |
|--------------------------|---|----------------------------|---------------|------------|---------|
| 12974 | 713257209 / 713279371 / 713313043 713316921 / 713316928 / 713316930 713316916 / 713316919 / 713316912 | medical_devices@tuvsud.com | | 2024-04-23 | 1 of 50 |

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 012974 0657 Rev. 00**

**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.

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
(Germany) at tuvsud.com/imprint

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

TÜV SÜD Product Service GmbH
Ridlerstr. 65
80339 Munich
Germany

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

TUV®



- 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.

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._00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-23

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in blue ink, appearing to be 'JKunte', written over a horizontal line.

SIGN-ID 607854
23.04.2024

Jürgen Kunte

Jürgen Kunte
Conformity Assessment Responsible (CARE)

A handwritten signature in black ink, appearing to be 'Polyana GFV Heimes', written over a horizontal line.

Polyana GF Vilela Heimes
Application Reviewer



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 Compact plus | 8717030 | N/A | 403923900000038ZM | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| Infusomat Compact plus | 8717050 | N/A | 40392390000005352B | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| OnlineSuite | 876100 | N/A | 40392390000005552H | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| Spaceplus Perfusor | 8719030 | N/A | 40392390000007562V | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| Spaceplus Infusomat | 8719050 | N/A | 40392390000007552T | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| Infusomat Compact plus P | 8717070 | N/A | 40392390000007492Y | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| Sangofix® Air | 4116011F | N/A | 4039239000000039ZP | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Omnifix® Lock | 4617006 | N/A | 4039239000000044ZG | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Omnican fine | 932M04SE | N/A | 40392390000018743B | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Omnican fine | 931M08SE | N/A | | | |
| Drainobag® 600 V | 5523606 | N/A | 40392390000007973B | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Drug Library Manager Spaceplus | 876203 | N/A | 403923900000169000 | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| Drug Library Manager Spaceplus | 876209 | N/A | 403923900000169539 | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| GLYCINE 1,5 % B. BRAUN | FR29914 | N/A | 403923900000249638 | class IIb | G1 012974 0607 Rev. 02 |
| GLYCINE 1,5 % B. BRAUN | FREU914 | 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 |
|------------------------|--|---|--------------------------------------|--|--|
| GLYCINE 1,5 % B. BRAUN | FREU934 | N/A | | | NB0123 |
| GLYCINE 1,5 % B. BRAUN | FREU954 | N/A | | | |
| 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 | | | |
| NaCl 0,9 % B. BRAUN | 3637006 | N/A | | | |
| NaCl 0,9 % B. BRAUN | 0069414E | N/A | 40392390000026312N | class IIb | G1 012974 0607 Rev. 02 NB0123 |
| 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 | | | |
| Vitulia | 450268 | N/A | | | |
| 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 % 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 | N/A | 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 | | | |
| 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 | | | |
| Perifix Catheter Connector | 4513800 | N/A | | | |
| Perifix Catheter Connector | 4513801 | N/A | | | |
| Perifix Catheter Connector NRFit | 4513800N-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 |
|----------------------------------|--|---|--------------------------------------|--|--|
| 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 Safe-Set | 8700200 | N/A | 40392390000008622V | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Infusomat® Plus Line Safe-Set | 8700200-20 | N/A | | | |
| Infusomat® Plus Line Safe-Set | 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 | | | |



| 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® 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 | 403923900000078432 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Cyto-Set® Line | A2582NF | N/A | | | |
| Cyto-Set® Mix | A2900N | N/A | | | |
| Cyto-Set® Mix | A2903N | N/A | | | |
| Cyto-Set® Mix | A2906N | N/A | | | |
| Cyto-Set® Mix | A2907N | N/A | | | |
| Cyto-Set® Mix | A2908N | N/A | | | |
| Stimuplex® A | 4894251 | N/A | 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 | | | |



| 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 270-27 | 4540008-07 | N/A | | | |
| Easypump® II LT 270-27 | 4540008-20 | N/A | | | |
| Easypump® II LT 60-30 | 4540010 | N/A | | | |
| Easypump® II LT 60-30 | 4540010-07 | N/A | | | |
| Easypump® II LT 60-30 | 4540010-20 | N/A | | | |
| Easypump® II LT 120-30 | 4540012 | N/A | | | |
| Easypump® II LT 120-30 | 4540012-07 | N/A | | | |
| Easypump® II LT 120-30 | 4540012-20 | N/A | | | |
| Easypump® II LT 400-40 | 4540014 | N/A | | | |
| Easypump® II LT 400-40 | 4540014-07 | N/A | | | |
| Easypump® II LT 400-40 | 4540014-20 | N/A | | | |
| Easypump® II LT 100-50 | 4540016 | N/A | | | |
| Easypump® II LT 100-50 | 4540016-07 | N/A | | | |
| Easypump® II LT 100-50 | 4540016-20 | N/A | | | |
| Easypump® II LT 270-54 | 4540018 | N/A | | | |
| 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 | | | |



| 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 ST 250-1 | 4540048-07 | N/A | | | |
| Easypump® II ST 250-1 | 4540048-20 | N/A | | | |
| Easypump® II ST 250-1,5 | 4540050 | N/A | | | |
| Easypump® II ST 250-1,5 | 4540050-07 | N/A | | | |
| Easypump® II ST 250-1,5 | 4540050-20 | N/A | | | |
| Easypump® II ST 400-2 | 4540052 | N/A | | | |
| Easypump® II ST 400-2 | 4540052-07 | N/A | | | |
| Easypump® II ST 400-2 | 4540052-20 | N/A | | | |
| Easypump® II ST 500-2 | 4540054 | N/A | | | |
| Easypump® II ST 500-2 | 4540054-07 | N/A | | | |
| Easypump® II ST 500-2 | 4540054-20 | N/A | | | |
| Easypump® II ST 100-2 | 4540056 | N/A | | | |
| Easypump® II ST 100-2 | 4540056-07 | N/A | | | |
| Easypump® II ST 100-2 | 4540056-20 | N/A | | | |
| Easypump® II ST 400-4 | 4540058 | N/A | | | |
| Easypump® II ST 400-4 | 4540058-07 | N/A | | | |
| Easypump® II ST 400-4 | 4540058-20 | N/A | | | |
| Spinal Introducer | 4505000-13 | 4505000 | 403923900000085836 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Spinal Introducer | 4500059-13 | 4500059 | | | |
| 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 | | | |



| 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 |
|------------------------------------|--|---|--------------------------------------|--|--|
| 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 | 4039239000007582Z | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Discofix® | 4095111 | N/A | | | |
| Discofix® | 4095120 | N/A | | | |
| Discofix® | 4095146 | N/A | | | |
| Discofix® | 4095111IN | N/A | | | |
| Discofix® | 409511CN | N/A | | | |
| Discofix® | 409512CN | N/A | | | |
| Discofix® | 16466 | N/A | | | |
| Discofix® | 4098102 | N/A | | | |
| Discofix® | 409810CN | N/A | | | |
| Discofix® | 4098218 | N/A | | | |
| Discofix® | 409821CN | N/A | | | |
| Discofix® | 4098501 | N/A | | | |
| Discofix® | 4098234 | N/A | | | |
| Discofix® | 4098080 | N/A | | | |
| Discofix® | 4055150 | N/A | | | |
| Discofix® | 4055145 | N/A | | | |
| Discofix® | 4055146 | N/A | | | |
| Discofix® | 4055149 | N/A | | | |
| Discofix® | 4055147 | N/A | | | |
| Discofix® | 4055148 | N/A | | | |
| Discofix® | 4099010 | 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 |
|---------------------------------|--|---|--------------------------------------|--|--|
| 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 EN-Fit® | 9246603 | 9246519 | 40392390000008172Q | class IIa | G1 019717 0032 Rev. 00 NB0123 B. Braun Avitum Italy S.p.A.** |
| Nutritub® Gastral Basic EN-Fit® | 9246602 | 9246518 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246601 | 9246516 9246550 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246600 | 9246515 9246592 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246599 | 9246514 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246598 | 9246513 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246597 | 9246541 9246543 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246596 | 9246512 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246595 | 9246517 9246525 9246533 9246535 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246594 | 9246509 9246511 | | | |
| Nutritub® Gastral Basic EN-Fit® | 9246593 | 9246508 | | | |
| Infusomat® Space Line | 8250832SP | 8250833SP | | | |
| Infusomat® Space Line | 8250834SP | 8250835SP | | | |
| IN-Stopper | 4238010 | N/A | 40392390000028583L | 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 | | | |



| 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 |
|--------------------------------------|--|---|--------------------------------------|--|--|
| Original Perfusor® Lines Type ENFit™ | 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 | 403923900000121823 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Injekt® 40 Duo | 9166432V | N/A | | | |
| Introcan Safety® 3 | 4251127-01 | N/A | 40392390000007652W | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Introcan Safety® 3 | 4251127-03 | N/A | | | |
| Introcan Safety® 3 | 4251127-04 | N/A | | | |
| Introcan Safety® 3 | 4251127IN | N/A | | | |
| Introcan Safety® 3 | 4251127JP | N/A | | | |
| Introcan Safety® 3 | 4251128-01 | N/A | | | |
| Introcan Safety® 3 | 4251128-03 | N/A | | | |
| Introcan Safety® 3 | 4251128-04 | N/A | | | |
| Introcan Safety® 3 | 4251128IN | N/A | | | |
| Introcan Safety® 3 | 4251128JP | N/A | | | |
| Introcan Safety® 3 | 4251129-01 | N/A | | | |
| Introcan Safety® 3 | 4251129-03 | N/A | | | |
| Introcan Safety® 3 | 4251129-04 | N/A | | | |
| Introcan Safety® 3 | 4251129JP | N/A | | | |
| Introcan Safety® 3 | 4251130-01 | N/A | | | |
| 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 | | | |



| 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 | 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 | | | |
| Mini-Redovac® 50 K 6 | U2045001 | N/A | 403923900000080027 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Mini-Redovac® 50 K 8 | U2045003 | N/A | | | |
| 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 8721750 8721688 8721726 8721734 8721735 8721736 8721737 8721742 | 403923900000263732 | class IIa | G1 019717 0032 Rev. 00 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 |



| 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 |
|-----------------------------------|--|---|--------------------------------------|--|--|
| Extension Line, Type: Alargadera | 4094603 | N/A | | | Rev. 02 NB0123 |
| In-line injection tubing | 4247116 | N/A | | | |
| LS-3 Connector | 4053753 | N/A | 40392390000078738 | 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 | 4039239000007832Y | 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 | | | |
| 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 | | | |



| 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 | 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® Mix | 4182711 | N/A | | | |
| ProSet Cyto-Set® Mix | 4182726 | N/A | | | |
| ProSet Cyto-Set® Mix | 4182727 | N/A | | | |
| ProSet Cyto-Set® Line | 4182728 | N/A | | | |
| ProSet Cyto-Set® Mix | 4182729 | N/A | | | |
| ProSet Cyto-Set® Line | 4182734 | N/A | | | |
| ProSet Cyto-Set® Mix | 4182817 | N/A | | | |
| ProSet Cyto-Set® Mix | 4188090 | N/A | | | |
| ProSet Cyto-Set® Mix | 4188091 | N/A | | | |
| ProSet Cyto-Set® Mix | 4188092 | N/A | | | |
| ProSet Cyto-Set® Line | 4188093 | N/A | | | |
| 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 | A1673SO | 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 |



| 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 |
|------------------------------------|--|---|--------------------------------------|--|--|
| | | | | | 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 | | | |
| Introcán® Certo | 4055764 | N/A | 40392390000007612N | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Introcán® Certo | 4251300 | N/A | | | |
| Introcán® Certo | 4251318 | N/A | | | |
| Introcán® Certo | 4251326 | N/A | | | |
| Introcán® Certo | 4251334 | N/A | | | |
| Introcán® Certo | 4251342 | N/A | | | |
| Introcán® Certo | 4251350 | N/A | | | |
| Introcán® Certo | 4251369 | N/A | | | |
| Introcán® | 4252071B | N/A | | | |
| Introcán® | 4252098B | N/A | | | |
| Introcán® | 4252110B | N/A | | | |
| Introcán® | 4252136B | N/A | | | |
| Introcán® | 4252160B | N/A | | | |
| Introcán® | 4252217B | N/A | | | |
| Introcán® | 4252322B | 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®-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 | | | |
| Introcan®-W With In-stopper | 4258583 | N/A | | | |
| Introcan®-W With In-stopper | 4258584 | N/A | | | |
| Introcan®-W With In-stopper | 4258585 | N/A | | | |
| Introcan®-W With In-stopper | 4258586 | N/A | | | |
| Discofix® C Safeflow | 16494CCN | N/A | 4039239000007602L | 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 | 4039239000008082P | 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 | 40392390000075933 | class IIa | G1 012974 0607 Rev. 02 |
| Discofix® C | 16540C | 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 |
|-----------------------------|--|---|--------------------------------------|--|--|
| Discofix® C | 16494C | N/A | | | NB0123 |
| 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 | 4039239000007922Z | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Pleuracan® B | 4462505 | N/A | | | |
| Pleuracan® Back-Check Valve | 4462564 | N/A | 40392390000079333 | class IIa | G1 012974 0607 Rev. 02 NB0123 |



| 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 |
|-------------------------------|--|---|--------------------------------------|--|--|
| Drainobag® Lock 600 | 5523682 | N/A | 403923900000281736 | class IIa | G1 012974 0607 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 | | | |
| Introcan Safety® | 4251601-01 | N/A | 40392390000007632S | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Introcan Safety® | 4251601-03 | N/A | | | |
| Introcan Safety® | 4251601-04 | N/A | | | |
| Introcan Safety® | 4251601JP | N/A | | | |
| Introcan Safety® | 4251607-01 | N/A | | | |
| Introcan Safety® | 4251607-03 | N/A | | | |
| Introcan Safety® | 4251607-04 | N/A | | | |
| Introcan Safety® | 4251607JP | N/A | | | |
| Introcan Safety®-W | 4251614-01 | N/A | | | |
| Introcan Safety®-W | 4251614-03 | N/A | | | |
| Introcan Safety®-W | 4251614-04 | N/A | | | |
| Introcan Safety®-W | 4251614JP | N/A | | | |
| Introcan Safety® | 4251620-01 | N/A | | | |
| Introcan Safety® | 4251621-01 | N/A | | | |
| Introcan Safety® | 4251622-01 | N/A | | | |
| Introcan Safety® | 4251623-01 | N/A | | | |
| Introcan Safety® | 4251628-01 | N/A | | | |
| Introcan Safety® | 4251628-03 | N/A | | | |
| Introcan Safety® | 4251628-04 | N/A | | | |
| Introcan Safety® | 4251628JP | 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® | 4251644-01 | N/A | | | |
| Introcan Safety® | 4251644-03 | N/A | | | |
| Introcan Safety® | 4251644-04 | N/A | | | |
| Introcan Safety® | 4251644JP | N/A | | | |
| 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 | | | |



| 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® | 4252543-01 | N/A | | | |
| Introcan Safety® | 4252551-01 | N/A | | | |
| Introcan Safety® | 4252551-03 | N/A | | | |
| Introcan Safety® | 4252551-04 | N/A | | | |
| 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 | | | |



| 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 | 4253639-01 | N/A | | | |
| Introcan Safety®-W | 4253639-03 | N/A | | | |
| Introcan Safety®-W | 4253639JP | N/A | | | |
| Introcan Safety®-W | 4253639-04 | N/A | | | |
| 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 | | | |
| ProSet Intrapur® | 4183925 | N/A | | | |
| ProSet Intrapur® | 4183926 | N/A | | | |
| ProSet Intrapur® | 4183927 | N/A | | | |
| ProSet Intrapur® | 4183930 | N/A | | | |
| ProSet Intrapur® | 4183933 | N/A | | | |
| ProSet Intrapur® | 4183935 | N/A | | | |
| ProSet Intrapur® | 4183937 | N/A | | | |
| ProSet Intrapur® | 4183942 | N/A | | | |
| ProSet Intrapur® | 4183947 | 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 | | | |



| 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® | 4184008 | N/A | | | |
| ProSet Intrapur® | 4098725 | N/A | | | |
| ProSet Intrapur® | 4183936 | N/A | | | |
| ProSet Intrapur® | 4081002 | N/A | | | |
| ProSet Sterifix® Neonat | 4099265 | N/A | | | |
| ProSet Intrapur® | 4187822 | N/A | | | |
| ProSet Intrapur® | 4184001 | N/A | | | |
| ProSet Intrapur® | 4183255 | N/A | | | |
| ProSet Intrapur® | 4183245 | N/A | | | |
| ProSet Intrapur® | 4183240 | N/A | | | |
| ProSet Intrapur® | 4180351 | N/A | | | |
| ProSet Intrapur® | 4180350 | N/A | | | |
| ProSet 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 | | | |



| 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 | 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 | 4181232 | N/A | | | |
| ProSet Discifix® C | 4180439 | N/A | | | |
| 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 | | | |



| 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 | 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 | | | |
| 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 |
| Vasofix® Braunüle® | 4268113B | N/A | | | Rev. 02 |



| 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® Braunüle® | 4268130B | N/A | | | NB0123 |
| Vasofix® Braunüle® | 4268156B | N/A | | | |
| Vasofix® Braunüle® | 4268172B | N/A | | | |
| Vasofix® Braunüle® | 4268210B | N/A | | | |
| Vasofix® Braunüle® | 4268334B | N/A | | | |
| Vasofix® Certo | 4269071 | N/A | | | |
| Vasofix® Certo | 4269098 | N/A | | | |
| Vasofix® Certo | 4269110 | N/A | | | |
| Vasofix® Certo | 4269136 | N/A | | | |
| Vasofix® Certo | 4269152 | N/A | | | |
| Vasofix® Certo | 4269179 | N/A | | | |
| Vasofix® Certo | 4269217 | N/A | | | |
| Vasofix® Certo | 4269225 | N/A | | | |
| Vasofix® Certo | 4269330 | N/A | | | |
| Extension Line | 4051807 | N/A | 4039239000007893C | 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 | 4268091S-01 | N/A | 4039239000007642U | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Vasofix® Safety | 4268091S-03 | N/A | | | |
| Vasofix® Safety | 4268113S-01 | N/A | | | |
| Vasofix® Safety | 4268113S-03 | N/A | | | |
| Vasofix® Safety | 4268130S-01 | N/A | | | |
| Vasofix® Safety | 4268130S-03 | N/A | | | |
| Vasofix® Safety | 4268156S-01 | N/A | | | |
| Vasofix® Safety | 4268156S-03 | N/A | | | |
| Vasofix® Safety | 4268172S-01 | N/A | | | |
| Vasofix® Safety | 4268172S-03 | N/A | | | |
| Vasofix® Safety | 4268210S-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 |
|--------------------|--|---|--------------------------------------|--|--|
| Vasofix® Safety | 4268210S-03 | N/A | | | |
| Vasofix® Safety | 4268334S-01 | N/A | | | |
| Vasofix® Safety | 4268334S-03 | N/A | | | |
| Vasofix® Safety | 4269071S-01 | N/A | | | |
| Vasofix® Safety | 4269071S-03 | N/A | | | |
| Vasofix® Safety | 4269071SIN | N/A | | | |
| Vasofix® Safety | 4269071S-20 | N/A | | | |
| Vasofix® Safety | 4269098S-01 | N/A | | | |
| Vasofix® Safety | 4269098S-03 | N/A | | | |
| Vasofix® Safety | 4269098SIN | N/A | | | |
| Vasofix® Safety | 4269098S-20 | N/A | | | |
| Vasofix® Safety | 4269110S-01 | N/A | | | |
| Vasofix® Safety | 4269110S-03 | N/A | | | |
| Vasofix® Safety | 4269110SIN | N/A | | | |
| Vasofix® Safety | 4269110S-20 | N/A | | | |
| Vasofix® Safety | 4269136S-01 | N/A | | | |
| Vasofix® Safety | 4269136S-03 | N/A | | | |
| Vasofix® Safety | 4269136SIN | N/A | | | |
| Vasofix® Safety | 4269136S-20 | N/A | | | |
| Vasofix® Safety | 4269152S-01 | N/A | | | |
| Vasofix® Safety | 4269152S-03 | N/A | | | |
| Vasofix® Safety | 4269152S-20 | N/A | | | |
| Vasofix® Safety | 4269179S-01 | N/A | | | |
| 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 | 4039239000007893C | 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 | | | |



| 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 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 | | | |
| 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 Safe-Set | 8700390 | N/A | 40392390000014782X | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Infusomat@plus Line Safe-Set | 8700391 | N/A | | | |
| Infusomat@plus Line Safe-Set | 8700392 | N/A | 403923900000259235 | class IIa | G1 012974 0607 Rev. 02 |



| 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 |
|-------------------------------|--|---|--------------------------------------|--|--|
| | | | | | 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 NB0123 |
| Drainobag® Lock 300 | 5522390 | N/A | | | |
| Drainobag® 150 | 5523753 | N/A | | | |
| Drainobag® Lock 150 | 5523761 | N/A | | | |
| Drainobag® Lock 150 | 55237611 | N/A | | | |
| Drainobag® Bayonet 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 | | | |



| 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 |
|----------------------------|--|---|--------------------------------------|--|--|
| 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® Bayonet 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 | | | |
| Drainobag® Lock 600 K 12 | 5523428 | N/A | | | |
| Intrafix® SafeSet | 4063144 | N/A | 4039239000007812U | 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 | | | |
| ProSet Intrafix® Primeline | 4187005 | N/A | | | |
| ProSet Intrafix® SafeSet | 4187006 | N/A | | | |
| ProSet Intrafix® Primeline | 4187007 | N/A | | | |
| ProSet Intrafix® Primeline | 4187008 | 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 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 | | | |
| 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 |



| 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 | | | |
|--------------------------------|--|---|--------------------------------------|--|--|--------------------|-----------|-------------------------------------|
| | | | | | 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 Safe-Set | 8700240-20 | N/A | | | | | | |
| Infusomat® Plus Line Safe-Set | 8700280 | N/A | | | | | | |
| Infusomat® Plus Line Safe-Set | 8700300 | N/A | | | | | | |
| Infusomat® Plus Line | 8700340 | N/A | | | | | | |
| Infusomat® Plus Line Safe-Set | 8700250 | N/A | | | | | | |
| Infusomat® Plus Line Safe-Set | 8700240 | N/A | | | | | | |
| Infusomat® Plus Line Safe-Set | 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 | | | | | | |



| 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 Original Perfusor® Line | 4183968 | N/A | | | |
| ProSet Original Perfusor® Line | 4093000 | 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 NB0123 |
| Infusomat® Plus Line | 8700400 | N/A | | | |
| Infusomat® Plus Line | 8700370 | N/A | | | |
| Omnican® fine | 9167641WE | N/A | 4039239000001006ZF | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Omnican® fine | 9167650WE | N/A | | | |
| Omnican® fine | 9167668WE | N/A | | | |
| Omnican® fine | 9167684WE | N/A | | | |
| Omnican® fine | 9167820WE | N/A | | | |
| Omnican® fine | 929G12S-03 | N/A | | | |
| Omnican® fine | 929G12S-41 | N/A | | | |
| Omnican® fine | 929G12S-43 | N/A | | | |
| Omnican® fine | 931G04S-03 | N/A | | | |
| Omnican® fine | 931G04S-41 | N/A | | | |
| Omnican® fine | 931G04S-43 | N/A | | | |
| Omnican® fine | 931G04SCN | N/A | | | |
| Omnican® fine | 931G04SCN1 | N/A | | | |
| Omnican® fine | 931G06S-03 | 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 |
|-------------------------------|--|---|--------------------------------------|--|--|
| 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 Safe-Set | 8700270 | N/A | 40392390000020742A | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Infusomat® Plus Line Safe-Set | 8700260-20 | N/A | | | |
| Infusomat® Plus Line Safe-Set | 8700260 | N/A | | | |
| 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 Rev. 02 NB0123 |
| ProSet Infusomat® Space Line | 4180639SP | 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 Infusomat® Space Line | 4180020SP | N/A | | | |
| 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 | | | |



| 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 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 | | | |



| 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 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 | | | |
| 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 | | | |



| 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 Original Perfusor® Line | 4185687 | N/A | 4039239000008712W | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| ProSet Original Perfusor® Line | 4183972 | N/A | | | |
| 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 | | | |



| 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 |
|--------------------------------|--|---|--------------------------------------|--|--|
| Original Perfusor® Line | 8255059 | N/A | | | |
| ProSet Original Perfusor® Line | 4092933 | N/A | | | |
| 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 | 4039239000000039ZP | class IIa | G1 012974 0607 Rev. 02 |
| Sangofix® Air | 4050151 | 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 |
|-------------------------|--|---|--------------------------------------|--|--|
| Sangofix® | 4051998 | N/A | | | NB0123 |
| 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® fine | 931A04EUS | N/A | | | |
| 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 |
| IBSA FSH/LH | 9161530S | 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 | | | |
|------------------------------|--|---|--------------------------------------|--|--|--------------------|-----------|-------------------------------------|
| | | | | | NB0123 | | | |
| 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 | | | | | | |
| 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 | | | | | | |



| 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 |
|-------------------------|--|---|--------------------------------------|--|--|
| 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 | 403923900000207022 | 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 | | | |



| 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 |
|--------------------|--|---|--------------------------------------|--|--|
| 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® | 4666410 | 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 | | | |



| 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 |
|-------------------------|--|---|--------------------------------------|--|--|
| 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 | | | |
| Injekt® Luer Duo | 4645200V | N/A | | | |
| Injekt® Luer Duo | 4647220 | N/A | | | |
| Injekt®-F Luer Duo | 9166033V | N/A | | | |
| Sterican® Safety Needle | 4670030SBR | N/A | 403923900000076936 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Sterican® Safety Needle | 4670053SBR | N/A | | | |
| Contiplex® D | 4898323 | N/A | | | |
| 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 | 4898305NR | N/A | | | |
| Contiplex® D | 4898335NR | N/A | 40392390000008522S | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Contiplex® D | 4898311NR | N/A | | | |
| Contiplex® D | 4898323NR | N/A | | | |
| Contiplex® D | 4898325NR | N/A | | | |
| Contiplex® D | 4895819NCN | N/A | | | |
| Contiplex® D | 4894235NCN | N/A | | | |
| Contiplex® D | 4894243NCN | 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 | | | |
| Contiplex® C | 4898130 | N/A | 403923900000085632 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Contiplex® C | 4898115NR | N/A | | | |
| Contiplex® C | 4898130NR | N/A | | | |
| Ultraplex® 360 | 4892603-01 | N/A | | | |
| Ultraplex® 360 | 4892603CN | N/A | | | |
| Ultraplex® 360 NRFit® | 4892603NR-01 | N/A | 40392390000008552Y | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Ultraplex® 360 | 4892605-01 | N/A | | | |
| Ultraplex® 360 | 4892605CN | N/A | | | |
| Ultraplex® 360 NRFit® | 4892605NR-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 |
|-----------------------|--|---|--------------------------------------|--|--|
| 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 | | | |
| 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 | | | |



| 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 | | | |
|------------------------------|--|---|--------------------------------------|--|--|-------------------|-----------|-------------------------------------|
| 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 | | | | | | |
| 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 | | | | 403923900000044ZG | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Omnifix® Lock | 4617014 | N/A | | | | | | |
| Omnifix® Lock | 4617021 | N/A | | | | | | |
| Omnifix® Lock | 4617508F-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 |
|----------------------------------|--|---|--------------------------------------|--|--|
| Original Perfusor® Syringe 20 ml | 8728615 | N/A | 403923900000077939 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Original Perfusor® Syringe 20 ml | 8728615C | N/A | | | |
| Original Perfusor® Syringe 20 ml | 8728623 | N/A | 40392390000029923R | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Original Perfusor® Syringe 20 ml | 8728623C | N/A | | | |
| Original Perfusor® Syringe 50 ml | 8728810F-04 | N/A | | | |
| 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 | 403923900000077939 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Original Perfusor® Syringe 50 ml | 8728844F-06 | 8728844F | | | |
| Original Perfusor® Syringe 50 ml | 8728844F-20 | N/A | | | |
| Original Perfusor® Syringe 50 ml | 8728852F-04 | N/A | 40392390000029923R | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Original Perfusor® Syringe 50 ml | 8728852F-06 | N/A | | | |
| Original Perfusor® Syringe 50 ml | 8728852F-20 | N/A | | | |
| Original Perfusor® Syringe 50 ml | 8728861F-04 | N/A | 403923900000207124 | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Original Perfusor® Syringe 50 ml | 8728861F-06 | N/A | | | |
| Original Perfusor® Syringe 50 ml | 8728861F-20 | N/A | | | |
| Original Perfusor® Syringe 50 ml | 8728845F-01 | N/A | 40392390000007802S | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Cystofix® | 4450100 | N/A | 40392390000009993R | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Cystofix® | 4450120 | N/A | | | |
| Cystofix® | 4450130 | N/A | | | |
| Cystofix® | 4450150 | N/A | | | |
| Cystofix® | 4450160 | N/A | | | |
| Cystofix® | 4450170 | N/A | | | |
| Cystofix® | 4450180 | 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 | | | |
|----------------------|--|---|--------------------------------------|--|--|--------------------|-----------|-------------------------------------|
| Cystofix® | 4450200 | N/A | 4039239000001000Z3 | class IIb | G1 012974 0607 Rev. 02 NB0123 | | | |
| Cystofix® | 4450220 | N/A | | | | | | |
| Cystofix SG | 4450410 | N/A | 4039239000001002Z7 | class IIb | G1 022239 0080 Rev. 03 NB0123 B.BRAUN MEDICAL SAS*** | | | |
| Cystofix SG | 4450412 | N/A | | | | | | |
| Cystofix SG | 4450414 | N/A | | | | | | |
| Cystofix SG | 4450416 | N/A | | | | | | |
| Cystofix | 4450010 | N/A | 4039239000001001Z5 | class IIb | G1 022239 0080 Rev. 03 NB0123 B.BRAUN MEDICAL SAS*** | | | |
| Cystofix | 4450012 | N/A | | | | | | |
| Cystofix | 4450014 | N/A | | | | | | |
| Cystofix | 4450016 | N/A | | | | | | |
| Cystofix | 4450512 | N/A | | | | | | |
| Cystofix | 4450514 | N/A | | | | | | |
| 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 | | | | 40392390000009272Y | class IIa | G1 012974 0607 Rev. 02 NB0123 |
| Vasco® OP Powdered | 6031525 | N/A | | | | | | |
| Vasco® OP Powdered | 6031532 | N/A | | | | | | |
| 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 | | | | | | |



| 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 |
|------------------------------------|--|---|--------------------------------------|--|--|
| 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 | | | |
| Vasco® OP Free | 9208356 | N/A | | | |
| Vasco® OP Free | 9208364 | N/A | | | |
| Drainobag® Connection Tube Bayonet | 5524913 | U2170701 | | | |

** 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.



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 |