

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**Atraucan[®],
Atraucan[®] Paed,
Führungskanüle,
Pencan[®],
Pencan[®] Paed,
Pencan[®] Pencil Point,
Spinal Anästhesie Set,
Spinocan[®],
Universal Set,
Whitacre Nadel**

Kanülen zur Spinal-Anästhesie

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte**Konformitätsbewertungsverfahren**
nach Anhang II.3
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123hereby declare in our own responsibility
that the product/s**Atraucan[®],
Atraucan[®] Paed,
Guide Needle,
Pencan[®],
Pencan[®] Paed,
Pencan[®] Pencil Point,
Spinal Anaesthesia Kit,
Spinocan[®],
Universal Kit,
Whitacre Needle**

Needles for Spinal Anaesthesia

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices**Conformity Assessment Procedure**
according to annex II.3
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123

**Konformitätserklärung
Declaration of Conformity**Document-No.: **39.05.155a**Revision-No.: **07**Effective Date: **2009-02-25**Page: **2 of 5****Datum der ersten CE-Kennzeichnung**
1997-09**Date of first CE-marking**
1997-09

Melsungen, 2009-02-25

Melsungen, 2009-02-25

B. Braun Melsungen AG

B. Braun Melsungen AG

i. V.

i. V.


J. Heil
Vice President Quality & Environment Management
U. Goebel
Head of Regulatory Affairs CoE Pain Control & CVC

Konformitätserklärung
Declaration of ConformityDocument-No.: **39.05.155a**Revision-No.: **07**Effective Date: **2009-02-25**Page: **3 of 5****Anlage I / Attachment I**

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
16028	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16029	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16036	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16042	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16050	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16051	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16060	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16072	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
16102	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
333877	Pencan® Pencil Point	Pencan® Pencil Point	IIa
333877-05	Pencan®	Pencan®	IIa
4500059	Führungskanüle	Guide Needle	IIa
4500105	Führungskanüle	Guide Needle	IIa
4501144	Spinocan®	Spinocan®	IIa
4501195	Spinocan®	Spinocan®	IIa
4501373	Spinocan®	Spinocan®	IIa
4501390	Spinocan®	Spinocan®	IIa
4501900	Spinocan®	Spinocan®	IIa
4501918	Spinocan®	Spinocan®	IIa
4502013-13	Pencan®	Pencan®	IIa
4502019	Pencan®	Pencan®	IIa
4502019-01	Pencan®	Pencan®	IIa
4502019-10	Pencan®	Pencan®	IIa
4502027	Pencan®	Pencan®	IIa
4502027-01	Pencan®	Pencan®	IIa
4502027-10	Pencan®	Pencan®	IIa
4502035	Pencan®	Pencan®	IIa
4502035-13	Pencan®	Pencan®	IIa
4502043	Pencan®	Pencan®	IIa
4502043-13	Pencan®	Pencan®	IIa
4502051	Pencan®	Pencan®	IIa
4502051-13	Pencan®	Pencan®	IIa
4502116	Pencan®	Pencan®	IIa
4502116-13	Pencan®	Pencan®	IIa
4502120-13	Pencan®	Pencan®	IIa
4502124	Pencan®	Pencan®	IIa
4502124-13	Pencan®	Pencan®	IIa

Konformitätserklärung
Declaration of ConformityDocument-No.: **39.05.155a**Revision-No.: **07**Effective Date: **2009-02-25**Page: **4 of 5**

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
4502132	Pencan®	Pencan®	IIa
4502132-13	Pencan®	Pencan®	IIa
4502140	Spinocan®	Spinocan®	IIa
4502159	Pencan® Paed	Pencan® Paed	IIa
4502159-13	Pencan®	Pencan®	IIa
4502167	Pencan® Paed	Pencan® Paed	IIa
4502167-13	Pencan®	Pencan®	IIa
4502175	Pencan® Paed	Pencan® Paed	IIa
4502175-13	Pencan®	Pencan®	IIa
4502183	Pencan® Paed	Pencan® Paed	IIa
4502248	Pencan®	Pencan®	IIa
4502256	Pencan®	Pencan®	IIa
4502906	Spinocan®	Spinocan®	IIa
4503902	Spinocan®	Spinocan®	IIa
4504739	Atraucan®	Atraucan®	IIa
4504763	Atraucan® Paed	Atraucan® Paed	IIa
4504771	Atraucan® Paed	Atraucan® Paed	IIa
4504917	Spinocan®	Spinocan®	IIa
4505000	Führungskanüle	Guide Needle	IIa
4505506	Spinocan®	Spinocan®	IIa
4505751	Spinocan®	Spinocan®	IIa
4505905	Spinocan®	Spinocan®	IIa
4505913	Spinocan®	Spinocan®	IIa
4506014	Spinocan®	Spinocan®	IIa
4506090	Spinocan®	Spinocan®	IIa
4507401	Spinocan®	Spinocan®	IIa
4507754	Spinocan®	Spinocan®	IIa
4507908	Spinocan®	Spinocan®	IIa
4509200	Spinocan®	Spinocan®	IIa
4509757	Spinocan®	Spinocan®	IIa
4509900	Spinocan®	Spinocan®	IIa
4590384	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4590503	Whitacre Nadel	Whitacre Needle	IIa
4590600	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4590856	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4590899	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4591194	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4591666	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4591780	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4595360	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa

Konformitätserklärung
Declaration of Conformity

Document-No.: **39.05.155a**
Revision-No.: **07**
Effective Date: **2009-02-25**
Page: **5 of 5**

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
4596455	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4598539	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4598849	Spinal Anästhesie Set	Spinal Anaesthesia Kit	IIa
4599888	Universal Set	Universal Kit	IIa

My

B.Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Niemcy

oświadczamy niniejszym na naszą wyłączną odpowiedzialność, że produkt(y):

Atraucan[®],
Atraucan[®] Paed,
Igła Prowadząca,
Pencan[®],
Pencan[®] Paed,
Igła Penca[®] typu Pencil Point,
Zestaw do Znieczulania Kręgosłupowego,
Spinocan[®],
Zestaw Uniwersalny,
Igła Whitacre

Igły do Znieczulania Kręgosłupowego
(numery katalogowe w załączniku I)


spełnia(ją) wymagania następującej dyrektywy

Dyrektywa Rady nr 93/42/EEC z dnia 14 czerwca 1993
dot. Wyrobów Medycznych

Procedura Oceny Zgodności
zgodnie z załącznikiem II.3
Dyrektywy Rady wymienionej powyżej

Klasyfikacja
zgodnie z załącznikiem IX
Dyrektywy Rady wymienionej powyżej
Klasa IIa

Jednostka Notyfikująca
TÜV SÜD Product Service GmbH
Numer identyfikacyjny 0123

	Deklaracja Zgodności	Nr Dokumentu: Nr Przeglądu: Data wejścia w życie: Strona:	39.05.155a 07 2009-02-25 2 z 5
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Data pierwszego oznakowania znakiem CE
1997-09

Melsungen, 2009-02-25
B.Braun Melsungen AG

i.V.

/-/ podpis nieczytelny
J.Heil

Wice Prezes ds. Zarządzania Jakością
i Ochrony środowiska

Melsungen, 2009-02-25
B.Braun Melsungen AG

i.V.

/-/ podpis nieczytelny
U.Goebel

Kierownik Działu Stosunków
Prawnych CoE Kontrola Bólu & CVC

Załącznik I

Nr Kat.	Opis Produktu	Klasa
16028	Zestaw do Znieczulania kręgosłupowego	Ila
16029	Zestaw do Znieczulania kręgosłupowego	Ila
16036	Zestaw do Znieczulania kręgosłupowego	Ila
16042	Zestaw do Znieczulania kręgosłupowego	Ila
16050	Zestaw do Znieczulania kręgosłupowego	Ila
16051	Zestaw do Znieczulania kręgosłupowego	Ila
16060	Zestaw do Znieczulania kręgosłupowego	Ila
16072	Zestaw do Znieczulania kręgosłupowego	Ila
16102	Zestaw do Znieczulania kręgosłupowego	Ila
333877	Igła Pencan® typu Pencil Point	Ila
333877-05	Pencan®	Ila
4500059	Igła Prowadząca	Ila
4500105	Igła Prowadząca	Ila
4501144	Spinocan®	Ila
4501195	Spinocan®	Ila
4501373	Spinocan®	Ila
4501390	Spinocan®	Ila
4501900	Spinocan®	Ila
4501918	Spinocan®	Ila
4502013-13	Pencan®	Ila
4502019	Pencan®	Ila
4502019-01	Pencan®	Ila
4502019-10	Pencan®	Ila
4502027	Pencan®	Ila
4502027-01	Pencan®	Ila
4502027-10	Pencan®	Ila
4502035	Pencan®	Ila
4502035-13	Pencan®	Ila
4502043	Pencan®	Ila
4502043-13	Pencan®	Ila
4502051	Pencan®	Ila
4502051-13	Pencan®	Ila
4502116	Pencan®	Ila
4502116-13	Pencan®	Ila
4502120-13	Pencan®	Ila
4502124	Pencan®	Ila
4502124-13	Pencan®	Ila

Nr Kat.	Opis Produktu	Klasa
4502132	Pencan®	Ila
4502132-13	Pencan®	Ila
4502140	Spinocan® Paed	Ila
4502159	Pencan® Paed	Ila
4502159-13	Pencan®	Ila
4502167	Pencan® Paed	Ila
4502167-13	Pencan®	Ila
4502175	Pencan® Paed	Ila
4502175-13	Pencan®	Ila
4502183	Pencan® Paed	Ila
4502248	Pencan®	Ila
4502256	Pencan®	Ila
4502906	Spinocan®	Ila
4503902	Spinocan®	Ila
4504739	Atraucan®	Ila
4504763	Atraucan® Paed	Ila
4504771	Atraucan® Paed	Ila
4504917	Spinocan®	Ila
4505000	Igła Prowadząca	Ila
4505506	Spinocan®	Ila
4505751	Spinocan®	Ila
4505905	Spinocan®	Ila
4505913	Spinocan®	Ila
4506014	Spinocan®	Ila
4506090	Spinocan®	Ila
4507401	Spinocan®	Ila
4507754	Spinocan®	Ila
4507908	Spinocan®	Ila
4509200	Spinocan®	Ila
4509757	Spinocan®	Ila
4509900	Spinocan®	Ila
4590384	Zestaw do Znieczuleń Kręgosłupowych	Ila
4590503	Igła Whitacre	Ila
4590600	Zestaw do Znieczuleń Kręgosłupowych	Ila
4590856	Zestaw do Znieczuleń Kręgosłupowych	Ila
4590899	Zestaw do Znieczuleń Kręgosłupowych	Ila
4591194	Zestaw do Znieczuleń Kręgosłupowych	Ila
4591666	Zestaw do Znieczuleń Kręgosłupowych	Ila
4591780	Zestaw do Znieczuleń Kręgosłupowych	Ila
4595360	Zestaw do Znieczuleń Kręgosłupowych	Ila

Nr Kat.	Opis Produktu	Klasa
4596455	Zestaw do Znieczuleń Kręgosłupowych	Ila
4598539	Zestaw do Znieczuleń Kręgosłupowych	Ila
4598849	Zestaw do Znieczuleń Kręgosłupowych	Ila
4599888	Zestaw Uniwersalny	Ila

Konformitätserklärung
Declaration of ConformityRevision-No.: **08**Effective Date: **2012-03-01**Page: **1 of 4**

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germanyerklären in eigener Verantwortung,
dass das/die Produkt/ehereby declare in our own responsibility
that the product/s**Espocan®**

Katheter-Sets zur Spinal-Epidural-Anästhesie (CSE)

Espocan®

Catheter sets for spinal/epidural anaesthesia (CSE)

Perifix®,
Perifix® Complete Set (LOR) mit
Soft Tip Katheter,
Perifix® Katheter,
Perifix® ONE,
Perifix® ONE Complete Set,
Perifix® ONE Complete Set (LOR),
Perifix® ONE Katheter,
Perifix® ONE Paed,
Perifix® Paed,
Perifix® Soft,
Perifix® Soft Katheter,
Perifix® Soft Tip
Katheter zur Epidural-Anästhesie**Perifix®,**
Perifix® Complete Set (LOR) with
Soft Tip Catheter,
Perifix® Catheter,
Perifix® ONE,
Perifix® ONE Complete Set,
Perifix® ONE Complete Set (LOR),
Perifix® ONE Catheter,
Perifix® ONE Paed,
Perifix® Paed,
Perifix® Soft,
Perifix® Soft Catheter,
Perifix® Soft Tip
Catheters for epidural anaesthesia

(Artikelnummern siehe Anlage I)

(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EGCouncil Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC**Konformitätsbewertungsverfahren**
nach Anhang II.3 und II.4
der oben genannten Richtlinie**Conformity Assessment Procedure**
according to annex II.3 and II.4
of the Council Directive named above**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse III**Classification**
according to annex IX of the
Council Directive named above
Class III**Effective**

Konformitätserklärung
Declaration of ConformityDocument-No.: **39.05.157b** **Effective**Revision-No.: **08**Effective Date: **2012-03-01**Page: **2 of 4****Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
1997-01**Gültig bis**
2017-02-12**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Date of first CE-marking**
1997-01**Valid until**
2017-02-12

Melsungen, 2012-03-01

B. Braun Melsungen AG

i. V.


J. Heil
Vice President Quality & Environment Management

Melsungen, 2012-03-01

B. Braun Melsungen AG

i. V.


U. Goebel
Head of Regulatory Affairs CoE Pain Control & CVC**Effective**

Konformitätserklärung
Declaration of ConformityRevision-No.: **08**Effective Date: **2012-03-01**Page: **3 of 4****Anlage I / Attachment I**

Art.-Nr. / Art. No.	Produktname	Product name	Klasse / Class
4050114	Perifix® Complete Set (LOR) mit Soft Tip Katheter	Perifix® Complete Set (LOR) with Soft Tip Catheter	III
4050115	Perifix® ONE Complete Set	Perifix® ONE Complete Set	III
4056841	Perifix® ONE Complete Set (LOR)	Perifix® ONE Complete Set (LOR)	III
4454911	Perifix®	Perifix®	III
4510097	Perifix® Soft Tip	Perifix® Soft Tip	III
4510216	Perifix® Soft Tip	Perifix® Soft Tip	III
4510224	Perifix® Soft Tip	Perifix® Soft Tip	III
4510291	Perifix® Soft Tip	Perifix® Soft Tip	III
4510305	Perifix® Soft Tip	Perifix® Soft Tip	III
4511000	Perifix®	Perifix®	III
4511107	Perifix®	Perifix®	III
4512006	Perifix® Paed	Perifix® Paed	III
4512006C	Perifix® ONE Paed	Perifix® ONE Paed	III
4512014	Perifix® Paed	Perifix® Paed	III
4512014C	Perifix® ONE Paed	Perifix® ONE Paed	III
4512170	Perifix® Soft Katheter	Perifix® Soft Catheter	III
4512260	Perifix® Soft Katheter	Perifix® Soft Catheter	III
4513002	Perifix®	Perifix®	III
4513010	Perifix®	Perifix®	III
4513029	Perifix®	Perifix®	III
4513100	Perifix®	Perifix®	III
4513150	Perifix® Katheter	Perifix® Catheter	III
4513150C	Perifix® ONE Katheter	Perifix® ONE Catheter	III
4513177	Perifix® Katheter	Perifix® Catheter	III
4513258	Perifix® Katheter	Perifix® Catheter	III
4513258C	Perifix® ONE Katheter	Perifix® ONE Catheter	III
4514009	Perifix®	Perifix®	III
4514009C	Perifix® ONE	Perifix® ONE	III
4514017	Perifix®	Perifix®	III
4514017C	Perifix® ONE	Perifix® ONE	III
4514025	Perifix®	Perifix®	III
4514025C	Perifix® ONE	Perifix® ONE	III
4514050	Perifix®	Perifix®	III
4514050C	Perifix® ONE	Perifix® ONE	III
4514183C	Perifix® ONE	Perifix® ONE	III
4514203	Perifix®	Perifix®	III
4514203C	Perifix® ONE	Perifix® ONE	III

Konformitätserklärung
Declaration of ConformityDocument-No.: **39.05.157b** **Effective**Revision-No.: **08**Effective Date: **2012-03-01**Page: **4 of 4**

Art.-Nr. / Art. No.	Produktname	Product name	Klasse / Class
4514211	Perifix®	Perifix®	III
4514211C	Perifix® ONE	Perifix® ONE	III
4514300	Perifix®	Perifix®	III
4514300C	Perifix® ONE	Perifix® ONE	III
4514319	Perifix®	Perifix®	III
4514319C	Perifix® ONE	Perifix® ONE	III
4514505	Perifix®	Perifix®	III
4514513	Perifix®	Perifix®	III
4514513C	Perifix® ONE	Perifix® ONE	III
4515005	Perifix® Soft	Perifix® Soft	III
4515013	Perifix® Soft	Perifix® Soft	III
4515021	Perifix® Soft	Perifix® Soft	III
4515056	Perifix® Soft	Perifix® Soft	III
4515048	Perifix® Soft Tip	Perifix® Soft Tip	III
4515200	Perifix® Soft	Perifix® Soft	III
4515218	Perifix® Soft	Perifix® Soft	III
4515307	Perifix® Soft	Perifix® Soft	III
4515315	Perifix® Soft	Perifix® Soft	III
4516206	Perifix®	Perifix®	III
4517309	Perifix® Soft Tip	Perifix® Soft Tip	III
4517504	Perifix® Soft Tip	Perifix® Soft Tip	III
4556666	Espocan®	Espocan®	III
4556674	Espocan®	Espocan®	III
4556682	Espocan®	Espocan®	III
4556704	Espocan®	Espocan®	III
4556747	Espocan®	Espocan®	III
4556755	Espocan®	Espocan®	III
4556763	Espocan®	Espocan®	III

Effective

My

**B.Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Niemcy**

oświadczamy niniejszym na naszą wyłączną odpowiedzialność, że produkt(y):

Espocan®,

Zestawy z cewnikiem do znieczulenia rdzeniowego i zewnątrzoponowego (CSE)

Perifix®,

Kompletny Zestaw Perifix® (LOR) zawierający

Cewnik z Miękką Końcówką,

Cewnik Perifix®,

Perifix® ONE,

Kompletny Zestaw Perifix® ONE,

Kompletny Zestaw Perifix® ONE (LOR),

Cewnik Perifix® ONE,

Perifix® ONE Paed,

Perifix® Paed,

Perifix® Soft,

Cewnik Perifix® Soft,

Perifix® Soft Tip

Cewniki do znieczulenia zewnątrzoponowego

(numery katalogowe w załączniku I)

spełniają wymagania następującej dyrektywy

Dyrektywa Rady nr 93/42/EEC z dnia 14 czerwca 1993
dot. Wyrobów Medycznych
zmieniona Dyrektywą 2007/47/EC

Procedura Oceny Zgodności

zgodnie z załącznikiem II.3 i II.4

Dyrektywy Rady wymienionej powyżej

Klasyfikacja

zgodnie z załącznikiem IX

Dyrektywy Rady wymienionej powyżej

Klasa III

Deklaracja Zgodności

Nr Dokumentu: 39.05.157b
Nr Przeglądu: 08
Data wejścia w życie: 2012-03-01
Strona: 2 z 4

Jednostka Notyfikowana
TÜV SÜD Product Service GmbH
Numer identyfikacyjny 0123

Data pierwszego oznakowania znakiem CE
1997-01

Data ważności
2017-02-12

Melsungen, 2012-03-01
B.Braun Melsungen AG

i.V.

/-/ podpis nieczytelny
J.Heil

**W-ce Prezes ds. Zapewnienia Jakości
I Ochrony Środowiska**

Melsungen, 2012-03-01
B.Braun Melsungen AG

i.V.

/-/ podpis nieczytelny
U.Goebel

**Kierownik Działu Stosunków Prawnych
ds. Leczenia Bólu & CVC**

Załącznik I

Numer katalogowy	Opis	Klasa
4050114	Kompletny Zestaw Perifix® (LOR) zawierający Cewnik z Miękką Końcówką	III
4050115	Kompletny Zestaw Perifix® ONE	III
4056841	Kompletny Zestaw Perifix® ONE (LOR)	III
4454911	Perifix®	III
4510097	Perifix® Soft Tip	III
4510216	Perifix® Soft Tip	III
4510224	Perifix® Soft Tip	III
4510291	Perifix® Soft Tip	III
4510305	Perifix® Soft Tip	III
4511000	Perifix®	III
4511107	Perifix®	III
4512006	Perifix® Paed	III
4512006C	Perifix® ONE Paed	III
4512014	Perifix® Paed	III
4512014C	Perifix® ONE Paed	III
4512170	Cewnik Perifix® Soft	III
4512260	Cewnik Perifix® Soft	III
4513002	Perifix®	III
4513010	Perifix®	III
4513029	Perifix®	III
4513100	Perifix®	III
4513150	Cewnik Perifix®	III
4513150C	Cewnik Perifix® ONE	III
4513177	Cewnik Perifix®	III
4513258	Cewnik Perifix®	III
4513258C	Cewnik Perifix® ONE	III
4514009	Perifix®	III
4514009C	Perifix® ONE	III
4514017	Perifix®	III
4514017C	Perifix® ONE	III
4514025	Perifix®	III
4514025C	Perifix® ONE	III
4514050	Perifix®	III
4514050C	Perifix® ONE	III
4514183C	Perifix® ONE	III
4514203	Perifix®	III
4514203C	Perifix® ONE	III

Numer katalogowy	Opis	Klasa
4514211	Perifix®	III
4514211C	Perifix® ONE	III
4514300	Perifix®	III
4514300C	Perifix® ONE	III
4514319	Perifix®	III
4514319C	Perifix® ONE	III
4514505	Perifix®	III
4514513	Perifix®	III
4514513C	Perifix® ONE	III
4515005	Perifix® Soft	III
4515013	Perifix® Soft	III
4515021	Perifix® Soft	III
4515056	Perifix® Soft	III
4515048	Perifix® Soft Tip	III
4515200	Perifix® Soft	III
4515218	Perifix® Soft	III
4515307	Perifix® Soft	III
4515315	Perifix® Soft	III
4516206	Perifix®	III
4517309	Perifix® Soft Tip	III
4517504	Perifix® Soft Tip	III
4556666	Espocan®	III
4556674	Espocan®	III
4556682	Espocan®	III
4556704	Espocan®	III
4556747	Espocan®	III
4556755	Espocan®	III
4556763	Espocan®	III



Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 18 04 12974 455

Manufacturer:**B. Braun Melsungen AG**

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

**Product
Category(ies):**

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

- Injection, Infusion, transfusion and nutrition
- Anaesthesia, emergency, intensive and home care
- Disinfecting, cleaning, rinsing
- Irrigation
- Cryotherapy
- Configured customized sets
- Medical devices for wound care
- Medical Gloves
- Sterile Solutions

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

Report No.:

713128918

Valid from:

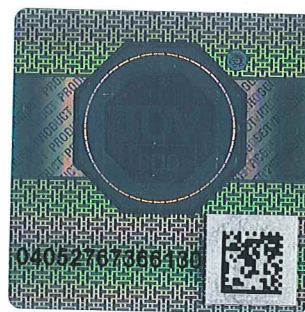
2018-05-11

Valid until:

2023-05-01

Date, 2018-05-11

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate**Full Quality Assurance System**

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

No. G1 18 04 12974 455

Facility(ies):

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

ALMO-Erzeugnisse Erwin Busch GmbH
Große Allee 84, 34454 Bad Arolsen, GERMANY

B. Braun Medical SAS
13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCE

B. BRAUN Vietnam Co., Ltd.
170 La Thanh Road, Dong Da District, 63000 Hanoi, VIETNAM

B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. Braun Medical Inc.
901 Marcon Boulevard, Allentown PA 18109-9341, USA

B. Braun Melsungen AG
Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

B.Braun Aesculap Japan Co., Ltd. Tochigi Factory - Hospital Care
285 Ogaki, Tsuga-machi, Tochigi-shi, Tochigi, 328-0101 JAPAN

B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. Braun Medical AG
Hauptstraße 39, 6182 Escholz matt, SWITZERLAND

B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi, VIETNAM

B. Braun Melsungen AG OPM
Carl-Braun-Straße 1, 34212 Melsungen, GERMANY

B. Braun Melsungen AG OPM
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B. Braun Medical AG
Seesatz 17, 6204 Sempach, SWITZERLAND



Product Service

CERTYFIKAT EC

Pełen System Zapewnienia Jakością

Dyrektywa 93/42/EEC dot. Wyrobów Medycznych (MDD), Załącznik II z wyłączeniem (4)

(Wyroby należące do klasy IIa, IIb lub III)

Nr G1 18 04 12974 455

Wytwórca:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
NIEMCY

Kategorie Produktów:

Nieaktywne wyroby medyczne (sterylne i nie sterylne) do

- Wstrzykiwań, infuzji, transfuzji i żywienia
- Anestezji, ratowania życia, intensywnej opieki i pielęgnacji domowej
- Dezynfekcji, mycia, płukania
- Irygacji
- Krioterapii
- Zestawy wykonywane na zamówienie klienta
- Wyroby medyczne do pielęgnacji ran
- Rękawice medyczne
- Roztwory sterylne

Jednostka certyfikująca TÜV SÜD Product Service GmbH oświadcza, że w/w wytwórca wdrożył system zapewniania jakości w zakresie projektowania, wytwarzania i kontroli końcowej w zakresie przedmiotowych wyrobów / kategorii wyrobów zgodnie z Załącznikiem II MDD. System zapewniania jakości jest zgodny z zaleceniami Dyrektywy i poddawany jest okresowym audytom. W celu wprowadzenia do obrotu wyrobów medycznych klasy III konieczne jest posiadanie dodatkowego certyfikatu na zgodność z wymaganiami Załącznika II (4). Patrz także informacje na odwrocie.

Raport nr: 713128918

Ważny od: 2018-05-11

Ważny do: 2023-05-01

Data, 2018-05-11

/-/podpis nieczytelny
Stefan Preiss

TÜV SÜD Product Service GmbH jest Jednostką Notyfikowaną o numerze identyfikacyjnym 0123.

Strona 1 z 2

TÜV SÜD Product Service GmbH – Miejsce certyfikacji – Ridlerstrasse 65 – 80339 Monachium - Niemcy

tłumaczenie: Biuro Tłumaczeń KWARTET, data tłumaczenia: 2018-05-14



Product Service

CERTYFIKAT EC

Pełen System Zapewnienia Jakością

Dyrektywa 93/42/EEC dot. Wyrobów Medycznych (MDD), Załącznik II z wyłączeniem (4)

(Wyroby należące do klasy IIa, IIb lub III)

Nr G1 18 04 12974 455

Miejsca wytwarzania:

B.Braun Melsungen AG

Carl-Braun-Str. 1, 34212 Melsungen, NIEMCY

Almo Erzeugnisse Erwin Busch GmbH

Grosse Allee 84, 34454 Bad Arolsen, NIEMCY

B.Braun Medical S.A.S.

13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCJA

B.Braun Vietnam Co., Ltd.

170 La Thanh Road, Dong Da District, 63000 Hanoi, WIETNAM

B.Braun Medical Kft Production Division

Deli-Kulhatar ut. 2-4, 3200 Gyöngyös, WĘGRY

B.Braun Medical Inc.

901 Marcon Boulevard, Allenown, PA 18103—9341, USA

B.Braun Melsungen AG

Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

B.Braun Aesculap Japan Co., Ltd., Tochigi Factory – Hospital Care

285 Ogaki, Tsuga-machi, Tochigi-shi, Tochigi, 328-0101 JAPONIA

B.Braun Medical Industries Sdn. Bhd.

Bayan Lepas Free Industrial Zone, 11900 Penang, MALEZJA

B.Braun Medical AG

Hauptstrasse 39, 6182 Escholz matt, SZWAJCARIA

B.Braun Vietnam Co., Ltd.

Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi, WIETNAM

B.Braun Melsungen AG OPM

Carl-Braun-Str. 1, 34212 Melsungen, NIEMCY

B.Braun Melsungen AG OPM

Schwarzenberger Weg 73-79, 34212 Melsungen, NIEMCY

B.Braun Medical AG

Seesatz 17, 6204 Sempach, SZWAJCARIA



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 04 12974 457

Manufacturer:

B. Braun Melsungen AGCarl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

Sterile non-active medical devices for

- Infusion, transfusion, nutrition and transfer devices
- Anaesthesia incl. accessories
- Urology, suction and drainage incl. accessories
- Catheterization and ventilation
- Oxygen therapy incl. accessories
- Incontinence
- Examination Gloves
- Wound care

**as well as related configured customized sets
Irrigation systems for diagnostic**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713128920

Valid from:

2018-05-02

Valid until:

2023-05-01



Date, 2018-04-27

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate**Production Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 04 12974 457**Facility(ies):**

B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. Braun Medical SAS
13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCE

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

B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi, VIETNAM

B. Braun Medical AG
Hauptstraße 39, 6182 Escholzmat, SWITZERLAND

ALMO-Erzeugnisse Erwin Busch GmbH
Große Allee 84, 34454 Bad Arolsen, GERMANY

B. BRAUN Vietnam Co., Ltd.
170 La Thanh Road, Dong Da District, 63000 Hanoi, VIETNAM

B. Braun Medical Inc.
901 Marcon Boulevard, Allentown PA 18109-9341, USA



Product Service

CERTYFIKAT EC

System Zapewnienia Jakości Produkcji

Dyrektywa 93/42/EEC dot. Wyrobów Medycznych (MDD), Załącznik V
(Wyroby klasy I sterylne, sterylne systemy i zestawy zabiegowe)

Nr G2S 18 04 12974 457

Wytwórca:

B. Braun Melsungen AG

Carl-Braun-Str. 1
34212 Melsungen
NIEMCY

Kategorie Produktów:

Sterylnie nieaktywne wyroby medyczne do

- Infuzji, transfuzji, żywienia i przelewania
- Anestezji, w tym akcesoria
- Urologii, odsysania i drenażu, w tym akcesoria
- Cewnikowania i odpowietrzania
- Terapii tlenowej, w tym akcesoria
- Nietrzymania moczu
- Rękawice diagnostyczne
- Pielęgnacji ran

jak również zestawy wykonywane na zamówienie klienta

Diagnostyczne Systemy do lrygacji

Jednostka Certyfikująca TÜV SÜD Product Service GmbH oświadcza, że w/w wytwórca wdrożył system zapewniania jakości w zakresie wytwarzania zgodnie z Załącznikiem V MDD. Niniejszy system zapewniania jakości obejmuje obszary wytwarzania dotyczące zabezpieczania i utrzymywania sterylności przedmiotowych produktów / kategorii produktów i zapewnienia zgodności z wymogami Dyrektywy. System zapewniania jakości jest poddawany okresowym audytom. Patrz również informacje na odwrocie.

Raport nr: 713128920

Ważny od: 2018-05-02

Ważny do: 2023-05-01

Data, 2018-04-27

/-/podpis nieczytelny
Stefan Preiss

TÜV SÜD Product Service GmbH jest Jednostką Notyfikowaną o numerze identyfikacyjnym 0123.

Strona 1 z 2

TÜV SÜD Product Service GmbH – Miejsce certyfikacji – Ridlerstrasse 65 – 80339 Monachium - Niemcy

tłumaczenie: Biuro Tłumaczeń KWARTET, data tłumaczenia: 2018-05-07



Product Service

CERTYFIKAT EC

System Zapewnienia Jakości Produkcji

Dyrektywa 93/42/EEC dot. Wyrobów Medycznych (MDD), Załącznik V
(Wyroby klasy I sterylne, sterylne systemy i zestawy zabiegowe)

Nr G2S 18 04 12974 457

Miejsca wytwarzania:

B.Braun Medical Kft Production Division
Deli-Kulhatar ut 2-4, 3200 Gyöngyös, WĘGRY

B.Braun Medical S.A.S.
13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCJA

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

B.Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone, 11900 Penang, MALEZJA

B.Braun Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi, WIETNAM

B.Braun Medical AG
Hauptstrasse 39, 6182 Escholzmat, SZWAJCARIA

ALMO-Erzeugnisse Erwin Busch GmbH
Grosse Allee 84, 34454 Bad Arolsen, NIEMCY

B.Braun Vietnam Co., Ltd.
170 La Thanh Road, Dong Da District, 63000 Hanoi, WIETNAM

B.Braun Medical, Inc.
901 Marcoun Boulevard, Allentown PA 18109-9341, USA

ORYGINAŁ

Pencan
Pencan PadZgłoszenie do rejestru wyrobu medycznego oznaczonego znakiem
zgodności CE, dla którego wystawiono deklarację zgodności

Form for the registration of the CE marked medical device placed on market

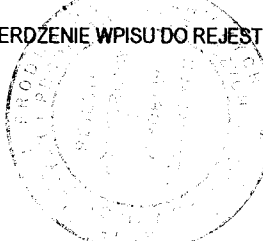
A.

1100	A. Dane organu kompetentnego / Identification of the Competent Authority Kod organu kompetentnego/ Code of competent authority ¹⁾		PL/CA 01
1110	Nazwa organu kompetentnego/ Name of competent authority ²⁾ Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych		
1120	Państwo/ Country ³⁾ Rzeczpospolita Polska PL	1130	Kraj związkowy / Federal Land ⁴⁾ —
1140	Miasto / City Warszawa	1150	Kod pocztowy / Postal code ⁶⁾ 00-725
1160	Ulica, nr domu, / Street, house no, ⁸⁾ Chelmska 30/34	1165	Skrytka poczt./ PO Box ⁶⁾ —
1190	Telefon/ Telephone no ⁸⁾ 851 43 81	1180	Faks / Fax no ⁸⁾ 851 52 43
1200	B. Dane rejestracji / Identification of the registration 03.02.2003 s. Data rejestracji przez organ kompetentny ⁵⁾ ⁶⁾ Date of registration at competent authority ⁵⁾ ⁶⁾		
1210	Numer identyfikacyjny wytwórcy ⁶⁾ Registration no ⁶⁾ PL/CA01 00003		
1240	Określenie zgłaszającego/ Status of the organisation submitting the registration application <input type="checkbox"/> 01 Wytwórca/ Manufacturer ⁹⁾ <input checked="" type="checkbox"/> 02 Autoryzowany przedstawiciel/ Authorized representative		
1250	C. Dane wytwórcy/ Identification of the manufacturer ¹⁰⁾ ⁸⁾ Numer identyfikacyjny/ Manufacturer code ¹⁰⁾ ⁸⁾ DE 812160059		
1260	Pełna nazwa wytwórcy/ Name of manufacturer, full B.BRAUN MELSUNGEN AG		
1265	Nazwa wytwórcy skrócona/ Name of manufacturer, shortened ⁹⁾ B.BRAUN		
1270	Państwo / Country ³⁾ DE / NIEMCY	1280	Kraj związkowy / Federal Land ⁴⁾ Hesse
1290	Miasto /City MELSUNGEN	1300	Kod pocztowy /Postal code D-34212
1310	Ulica, nr domu, nr lokalu / Street, house no, apptmt CARL-BRAUN-STRASSE 1	1315	Skrytka poczt./ PO Box Postfach 11 20
1320	Osoba wskazana do kontaktu/ Contact person ¹²⁾ Dr Wilhelm Wucherpennig	1330	Numer telefonów / Telephone numbers +49 56 61 71 29 34
1340	Numer faksów / Fax numbers +49 56 61 75 29 34	1350	E-mail wilhelm.wucherpennig@bbraun.com

1360	D. Dane autoryzowanego przedstawiciela Identification of the authorized representative ¹⁰⁾		
	<input checked="" type="checkbox"/> 02 Autoryzowany przedstawiciel/ Authorized representative		
1370	Numer identyfikacyjny autoryzowanego przedstawiciela / Authorized representative code ¹⁰⁾ PL 788-00-08-829		
1380	Nazwa/ nazwisko autoryzowanego przedstawiciela / Name of the authorized representative, full AESCULAP CHIFA Sp. z o.o.		
1390	Państwo / Country ³⁾ POLSKA	0003	Kraj związkowy / Federal State ⁴⁾ ---
0001	Miasto /City NOWY TOMYŚL	0004	Kod pocztowy /Postal code 64-300
0002	Ulica, nr domu, nr lokalu / Street, house no, apartment no TYSIĄCLECIA 14	0005	Skrytka poczt/ PO Box ---
1400	Osoba wskazana do kontaktu / Contact person ¹²⁾ MAREK ŁUKASZYK	1410	Numery telefonów / Telephone numbers (061) 44 20 290
1420	Numery faksów / Fax numbers (061) 44 20 295	1430	E-mail marek.lukaszyk@chifa.com.pl
0006	<p>Czy wytwórca wymieniony w części C jest już zarejestrowany w Europejskim Obszarze Gospodarczym jako wytwórca wyrobów medycznych?/ Is described in box C manufacturer already registered within European Economic Area as medical devices manufacturer?</p> <p><input type="checkbox"/> nie/ no <input checked="" type="checkbox"/> tak/ yes Jeżeli „tak” proszę podać datę i numer rejestracji If „yes” please fill date and registration number</p> <p>Czy wytwórca wymieniony w części C ma zarejestrowanego w Europejskim Obszarze Gospodarczym autoryzowanego przedstawiciela?/ Has described in box C manufacturer, authorized representative within European Economic Area?</p> <p><input checked="" type="checkbox"/> nie/ no <input type="checkbox"/> tak/ yes Jeżeli „tak” proszę podać datę i numer rejestracji If „yes” please fill date and registration number</p>		
0007	<p>Stwierdzam, że według mojej najlepszej wiedzy powyżej podane informacje są prawdziwe I affirm that the information given above is correct to best of my knowledge</p> <p>Miejscowość, data <i>Warszawa, dn. 09.05.2003</i> City, date</p> <p style="text-align: right;"> Aesculap Chifa Spółka z ograniczoną odpowiedzialnością <i>Agata Wacowska-Jastrzębska</i> Specjalista ds. Marketingu i Rejestracji </p> <p style="text-align: right;">Nazwisko i podpis..... Name and signature</p>		

B.

0009	Nazwa handlowa wyrobu, typ, wersje Product name, commercial name, product range, versions	1210	Numer Rejestru Wytwórców i Wyrobow Medycznych Registration No of manufacturer & medical device
	Igły do znieczuleń podpajęczynówkowych PENCAN[®], PENCAN Paed[®] z przewodnicą do igieł PENCAN[®]	0010	PL/CA01 <u>00003</u> PL/DR <u>000873</u>
1220	Podać czy jest to pierwszy wpis do rejestru, zmiana wpisu, wykreślenie z rejestru <input checked="" type="checkbox"/> 01 Pierwsza rejestracja / First <input type="checkbox"/> 02 Zmiana rejestracji/ change ¹⁾ <input type="checkbox"/> 03 Wykreślenie z rejestru/ withdrawal		
1230	W przypadku zmiany (02) lub wykreślenia z rejestru (03) podać poprzedni numer rejestru Previous registration number if registration changed (02) or withdrawn (03)		
1450	Nazwa techniczno-medyczna wyrobu według UMDNS (po polsku) ²⁾ Product generic name acc. to UMDNS (in Polish)	1445	Kod UMDNS ²⁾ UMDNS Code
1460	Nazwa techniczno-medyczna wyrobu według UMDNS (po angielsku) ²⁾ Product generic name acc. to UMDNS (in English)		
1480	Określenie kategorii wyrobu (po polsku) ³⁾ Product category description (in Polish) WYROBY JEDNORAZOWEGO UŻYCIA	1470	Kategoria wyrobu ³⁾ Product category 10
1490	Określenie kategorii wyrobu (po angielsku) ³⁾ Product category description (in English) SINGLE USE DEVICES		
1500	Krótki opis wyrobu medycznego i przewidziane przeznaczenie (po polsku) ⁴⁾ Short medical product description and intended use (in Polish) Igły PENCAN, PENCAN Paed przeznaczone są do znieczuleń podpajęczynówkowych. Jałowe, wyłącznie jednorazowego użytku		
1510	Krótki opis wyrobu medycznego i przewidziane przeznaczenie (po angielsku) ⁴⁾ Short medical product description and intended use (in English) PENCAN, PENCAN Paed needles are for spinal anaesthesia and diagnostic lumbar puncture. Sterile, single use only.		
1520	Klasyfikacja/Classification Nr Jedn. Notyfikowanej Notified Body ID <input type="checkbox"/> Klasa I reguła..... ⁵⁾ Class I rule <input type="checkbox"/> Klasy I sterylne ⁵⁾ Class I sterile <input type="checkbox"/> Klasy I z funkc. pomiar. ⁵⁾ Class I with measuring function	1530	Klasyfikacja / Classification Nr Jedn. Notyfikowanej Notified Body ID <input type="checkbox"/> Klasa IIa reguła..... ¹⁸⁾ Class IIa rule no <input checked="" type="checkbox"/> Klasa IIb reguła 6..... ¹⁸⁾ 0123 Class IIb rule no <input type="checkbox"/> Klasa III reguła..... ¹⁸⁾ Class III rule no
1525	Wyrób do diagnostyki in vitro z wyjątkiem wyrobu przeznaczonego do oceny działania In vitro diagnostic device <input type="checkbox"/> Lista A ⁵⁾ List A <input type="checkbox"/> Lista B ¹⁸⁾ <input type="checkbox"/> Do samodzielnego testowania List B Self testing IVD <input type="checkbox"/> Nie klasyfikowany do listy A albo B non- classified to list A or B ⁵⁾	1535	<input type="checkbox"/> Wyposażenie wyrobu medycznego ⁵⁾ Accessory for the medical device
		1550	<input type="checkbox"/> System lub zestaw zabiegowy ⁵⁾ System or procedure pack
1580	Opis systemu lub zestawu zabiegowego ⁵⁾ Description of system or procedure pack		

0011	Dokumenty dołączone do wniosku (zakreślić jeżeli są) Documents enclosed to the application (cross box if yes)	Oznaczenia i daty załączników Codes and dates of annexes
	<div data-bbox="261 254 834 1113"> <ul style="list-style-type: none"> ◆ Deklaracja zgodności Declaration of conformity <input checked="" type="checkbox"/> ◆ Instrukcja używania, etykiety i ulotka informacyjna ⁶⁾ <input checked="" type="checkbox"/> User's manual and labels ◆ Opis wyrobu ⁶⁾ <input type="checkbox"/> ◆ Product descriptions..... ◆ Opis procesu produkcji ⁶⁾ <input type="checkbox"/> ◆ Production process description..... ◆ Ocena kliniczna lub ocena działania ⁶⁾ <input type="checkbox"/> ◆ Clinical evaluation..... ◆ Protokoły badań ⁶⁾ <input type="checkbox"/> ◆ Test reports..... ◆ Wyniki analizy ryzyka ⁶⁾ <input type="checkbox"/> ◆ Risk analysis results..... ◆ Analiza zgodności z wymaganiami zasadniczymi ⁶⁾ <input type="checkbox"/> ◆ Essential requirements conformity analysis..... ◆ Certyfikat systemu jakości ⁶⁾ <input checked="" type="checkbox"/> ◆ Certificate of quality system..... ◆ Certyfikat oceny typu wyrobu ⁶⁾ <input type="checkbox"/> ◆ Certificate of type examination..... ◆ Opis procesu sterylizacji ⁶⁾ <input type="checkbox"/> ◆ Sterilisation process description..... ◆ Certyfikat parametrów pomiarowych ⁶⁾ <input type="checkbox"/> ◆ Measurement characteristics certificate..... ◆ Informacje wymagane dla wyrobów do diagnostyki in vitro ⁷⁾ <input type="checkbox"/> ◆ Information required for in vitro diagnostic medical devices..... ◆ Procedura nadzoru rynkowego ⁶⁾ <input type="checkbox"/> ◆ Vigilance system procedure..... ◆ Inne..... <input type="checkbox"/> ◆ Other..... ◆ Inne..... <input type="checkbox"/> ◆ Other..... </div>	<div data-bbox="1058 233 1318 728"> <p>39.05.155, 1997-09-08</p> <p>B. 01.5. 05. 98/2 Nr. 0604 0039 B.07.5.02. 99/1 Nr. 604 0004</p> <p>Q1Z 01 09 12974 243 2001-09-25</p> </div>
<p>Wszystkie załączone do wniosku dokumenty podlegają zwrotowi All documents enclosed to the application will be returned</p>		
0012	<p>Stwierdzam, że według mojej najlepszej wiedzy powyżej podane informacje są prawdziwe I affirm that the information given above is correct to best of my knowledge</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div data-bbox="258 1306 805 1374"> <p>Miejscowość, data <u>Warszawa, dn. 09.05.2003</u> City, date</p> </div> <div data-bbox="992 1279 1341 1419"> <p>Aesculap Chifa Spółka z ograniczoną odpowiedzialnością <i>Agata Wacowska-Jastrzębska</i> Specjalista ds. Marketingu i Rejestracji</p> </div> </div> <p style="text-align: center;">Nazwisko i podpis Name and signature</p>	
1660	<p>POTWIERDZENIE PRZYJĘCIA ZGŁOSZENIA O REJESTRACJĘ ¹⁾ Urząd Rejestracji Produktów Leczniczych Wyrobów Medycznych i Produktów Biobójczych ul. Chełmska 30/34, 00-725 Warszawa REGON 015249601</p> <div style="display: flex; justify-content: space-between;"> <div data-bbox="258 1691 406 1719"> <p>Pieczęć Urzędu</p> </div> <div data-bbox="810 1691 1201 1719"> <p>Nazwisko i podpis osoby przyjmującej <u><i>J. K. K...</i></u> Data wpływu. ¹⁾ <u>2003 -05- 12</u></p> </div> </div>	
0013	<p>POTWIERDZENIE WPISU DO REJESTRU ¹⁾</p> <div style="display: flex; justify-content: space-between;"> <div data-bbox="258 1732 626 2011">  <p>Pieczęć Urzędu</p> </div> <div data-bbox="670 1732 1341 2011"> <p>Urząd Rejestracji Produktów Leczniczych Wyrobów Medycznych i Produktów Biobójczych PREZES Prof. dr. hab. med. Michał Pirożyński <u><i>M. Pirożyński</i></u> Data ¹⁾ <u>2003 -06- 03</u></p> </div> </div>	

**Zgłoszenie do rejestru wyrobu medycznego oznaczonego znakiem
zgodności CE, dla którego wystawiono deklarację zgodności**

Form for the registration of the CE marked medical device placed on market

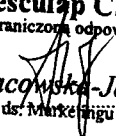
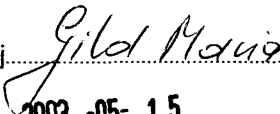
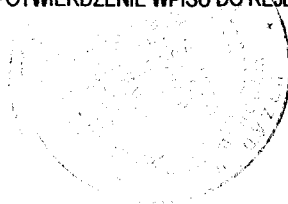
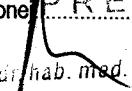
A.

1100	A. Dane organu kompetentnego / Identification of the Competent Authority Kod organu kompetentnego/ Code of competent authority ¹⁾		PL/CA 01
1110	Nazwa organu kompetentnego/ Name of competent authority ²⁾ <i>Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych</i>		
1120	Państwo/ Country ³⁾ <i>Rzeczpospolita Polska PL</i>	1130	Kraj związkowy / Federal Land ⁴⁾ _____
1140	Miasto / City <i>Warszawa</i>	1150	Kod pocztowy / Postal code ⁶⁾ <i>00-725</i>
1160	Ulica, nr domu, / Street, house no. ⁸⁾ <i>Chełmska 30/34</i>	1165	Skrytka poczt/ PO Box ⁶⁾ _____
1190	Telefon/ Telephone no ⁸⁾ <i>851 43 81</i>	1180	Faks / Fax no ⁸⁾ <i>851 52 43</i>
1200	B. Dane rejestracji / Identification of the registration <i>03.02.2003 r.</i> Data rejestracji przez organ kompetentny ⁵⁾ ⁶⁾ Date of registration at competent authority ⁵⁾ ⁶⁾		
1210	Numer identyfikacyjny wytwórcy ⁶⁾ Registration no ⁶⁾ PL/CA01 00003		
1240	Określenie zgłaszającego/ Status of the organisation submitting the registration application <input type="checkbox"/> 01 Wytwórca/ Manufacturer ⁹⁾ <input checked="" type="checkbox"/> 02 Autoryzowany przedstawiciel/ Authorized representative		
1250	C. Dane wytwórcy/ Identification of the manufacturer ¹⁰⁾ ⁸⁾ Numer identyfikacyjny/ Manufacturer code ¹⁰⁾ ⁸⁾ DE 812160059		
1260	Pełna nazwa wytwórcy/ Name of manufacturer, full B.BRAUN MELSUNGEN AG		
1265	Nazwa wytwórcy skrócona/ Name of manufacturer, shortened ⁹⁾ B.BRAUN		
1270	Państwo / Country ³⁾ DE / NIEMCY	1280	Kraj związkowy / Federal Land ⁴⁾ Hesse
1290	Miasto / City MELSUNGEN	1300	Kod pocztowy / Postal code D-34212
1310	Ulica, nr domu, nr lokalu / Street, house no, aptmt CARL-BRAUN-STRASSE 1	1315	Skrytka poczt/ PO Box Postfach 11 20
1320	Osoba wskazana do kontaktu/ Contact person ¹²⁾ Dr Wilhelm Wucherpennig	1330	Numerы telefonów / Telephone numbers +49 56 61 71 29 34
1340	Numerы faksów / Fax numbers +49 56 61 75 29 34	1350	E-mail wilhelm.wucherpennig@bbraun.com

1360	D. Dane autoryzowanego przedstawiciela Identification of the authorized representative ¹⁰⁾		
	<input checked="" type="checkbox"/> 02 Autoryzowany przedstawiciel/ Authorized representative		
1370	Numer identyfikacyjny autoryzowanego przedstawiciela / Authorized representative code ¹⁰⁾ PL 788-00-08-829		
1380	Nazwa/ nazwisko autoryzowanego przedstawiciela / Name of the authorized representative, full AESCULAP CHIFA Sp. z o.o.		
1390	Państwo / Country ³⁾ POLSKA	0003	Kraj związkowy / Federal State ⁴⁾ ---
0001	Miasto /City NOWY TOMYŚL	0004	Kod pocztowy /Postal code 64-300
0002	Ulica, nr domu, nr lokalu / Street, house no, apartment no TYSIĄCLECIA 14	0005	Skrytka poczt/ PO Box ---
1400	Osoba wskazana do kontaktu / Contact person ¹²⁾ MAREK ŁUKASZYK	1410	Numery telefonów / Telephone numbers (061) 44 20 290
1420	Numery faksów / Fax numbers (061) 44 20 295	1430	E-mail marek.lukaszyk@chifa.com.pl
0006	<p>Czy wytwórca wymieniony w części C jest już zarejestrowany w Europejskim Obszarze Gospodarczym jako wytwórca wyrobów medycznych?/ Is described in box C manufacturer already registered within European Economic Area as medical devices manufacturer?</p> <p><input type="checkbox"/> nie/ no <input checked="" type="checkbox"/> tak/ yes Jeżeli „tak” proszę podać datę i numer rejestracji If „yes” please fill date and registration number</p> <p>Czy wytwórca wymieniony w części C ma zarejestrowanego w Europejskim Obszarze Gospodarczym autoryzowanego przedstawiciela?/ Has described in box C manufacturer, authorized representative within European Economic Area?</p> <p><input checked="" type="checkbox"/> nie/ no <input type="checkbox"/> tak/ yes Jeżeli „tak” proszę podać datę i numer rejestracji If „yes” please fill date and registration number</p>		
0007	<p>Stwierdzam, że według mojej najlepszej wiedzy powyżej podane informacje są prawdziwe I affirm that the information given above is correct to best of my knowledge</p> <p>Miejscowość, data <u>Warszawa, dn. 13.05.2003</u> City, date</p> <p>Nazwisko i podpis..... Name and signature</p> <p style="text-align: right;"> Aesculap Chifa Spółka z ograniczoną odpowiedzialnością <i>Agata Wacowska-Jastrzębska</i> Specjalista ds. Marketingu i Rejestracji </p>		

B.

0009	Nazwa handlowa wyrobu, typ, wersje Product name, commercial name, product range, versions		Numer Rejestru Wytwórców i WYROBÓW MEDYCZNYCH Registration No of manufacturer & medical device
	ESPOCAN® zestaw do ciągłego jednoczesnego znieczulania podpajęczynówkowego i zewnątrzoponowego	1210 0010	PL/CA01 00003 PL/DR 000887
1220	Podać czy jest to pierwszy wpis do rejestru, zmiana wpisu, wykreślenie z rejestru <input checked="" type="checkbox"/> 01 Pierwsza rejestracja / First <input type="checkbox"/> 02 Zmiana rejestracji/ change ⁷⁾ <input type="checkbox"/> 03 Wykreślenie z rejestru/ withdrawal		
1230	W przypadku zmiany (02) lub wykreślenia z rejestru (03) podać poprzedni numer rejestru Previous registration number if registration changed (02) or withdrawn (03)		
1450	Nazwa techniczno-medyczna wyrobu według UMDNS (po polsku) ²⁾ Product generic name acc. to UMDNS (in Polish)	1445	Kod UMDNS ²⁾ UMDNS Code
1460	Nazwa techniczno-medyczna wyrobu według UMDNS (po angielsku) ²⁾ Product generic name acc. to UMDNS (in English)		
1480	Określenie kategorii wyrobu (po polsku) ³⁾ Product category description (in Polish) WYROBY JEDNORAZOWEGO UŻYCIA	1470	Kategoria wyrobu ³⁾ Product category 10
1490	Określenie kategorii wyrobu (po angielsku) ³⁾ Product category description (in English) SINGLE USE DEVICES		
1500	Krótki opis wyrobu medycznego i przewidziane przeznaczenie (po polsku) ⁴⁾ Short medical product description and intended use (in Polish) Zestaw do ciągłego jednoczesnego znieczulania podpajęczynówkowego i zewnątrzoponowego ESPOCAN® służy osiągnięciu szybkiej anestezji regionalnej do procedur operacyjnych. Jej działanie może być przedłużane, w miarę potrzeb zarówno w trakcie, jak też po zakończeniu operacji. Wyrób jałowy, wyłącznie jednorazowego użytku.		
1510	Krótki opis wyrobu medycznego i przewidziane przeznaczenie (po angielsku) ⁴⁾ Short medical product description and intended use (in English) Continous spinal and epidural anaesthesia set ESPOCAN® is for rapid anaesthesia for operative procedures which may be prolonged as required during and after the operation. Sterile, single use only		
1520	Klasyfikacja/Classification <input type="checkbox"/> Klasa I reguła..... ⁵⁾ Class I rule <input type="checkbox"/> Klasy I sterylne ⁵⁾ Class I sterile <input type="checkbox"/> Klasy I z funkc. pomiar. ⁵⁾ Class I with measuring function	Nr Jedn. Notyfikowanej Notified Body ID	1530 Klasyfikacja / Classification <input type="checkbox"/> Klasa IIa reguła..... ¹⁸⁾ Class IIa rule no <input type="checkbox"/> Klasa IIb reguła..... ¹⁸⁾ Class IIb rule no <input checked="" type="checkbox"/> Klasa III reguła...7..... ¹⁸⁾ 0123 Class III rule no
1525	Wyrób do diagnostyki in vitro z wyjątkiem wyrobu przeznaczonego do oceny działania In vitro diagnostic device <input type="checkbox"/> Lista A ⁵⁾ List A <input type="checkbox"/> Lista B ¹⁸⁾ List B <input type="checkbox"/> Nie klasyfikowany do listy A albo B non- classified to list A or B ⁵⁾	Jedn. Notyfikowana Notified Body ID	1535 <input type="checkbox"/> Wyposażenie wyrobu medycznego ⁵⁾ Accessory for the medical device ----- 1550 <input type="checkbox"/> System lub zestaw zabiegowy ⁵⁾ System or procedure pack -----
1580	Opis systemu lub zestawu zabiegowego ⁵⁾ Description of system or procedure pack Poszczególne zestawy zawierają (w różnych kombinacjach): igłę epiduralną PERICAN®, igłę spinalną SPINOCAN®, igłę spinalną z końcówką „pencil” Pencan®, cewnik epiduralny PERIFIX® (PERIFIX® Soft, PERIFIX® Soft Tip), łącznik śrubowy PERIFIX®, filtr (0,2um) PERIFIX®, strzykawka niskooporowa PERIFIX®, łącznik „docking system”, podkładkę PnPad PERIFIX®.		

0011	Dokumenty dołączone do wniosku (zakreślić jeżeli są) Documents enclosed to the application (cross box if yes)	Oznaczenia i daty załączników Codes and dates of annexes
	<div data-bbox="277 256 918 1113"> <ul style="list-style-type: none"> ◆ Deklaracja zgodności <input checked="" type="checkbox"/> Declaration of conformity ◆ Instrukcja używania, etykiety i ulotka informacyjna ⁶⁾ <input checked="" type="checkbox"/> User's manual and labels ◆ Opis wyrobu ⁶⁾ <input type="checkbox"/> Product descriptions ◆ Opis procesu produkcji ⁶⁾ <input type="checkbox"/> Production process description ◆ Ocena kliniczna lub ocena działania ⁶⁾ <input type="checkbox"/> Clinical evaluation ◆ Protokoły badań ⁶⁾ <input type="checkbox"/> Test reports ◆ Wyniki analizy ryzyka ⁶⁾ <input type="checkbox"/> Risk analysis results ◆ Analiza zgodności z wymaganiami zasadniczymi ⁶⁾ <input type="checkbox"/> Essential requirements conformity analysis ◆ Certyfikat systemu jakości ⁶⁾ <input checked="" type="checkbox"/> Certificate of quality system ◆ Certyfikat oceny typu wyrobu ⁶⁾ <input type="checkbox"/> Certificate of type examination ◆ Opis procesu sterylizacji ⁶⁾ <input type="checkbox"/> Sterilisation process description ◆ Certyfikat parametrów pomiarowych ⁶⁾ <input type="checkbox"/> Measurement characteristics certificate ◆ Informacje wymagane dla wyrobów do diagnostyki in vitro ⁷⁾ <input type="checkbox"/> Information required for in vitro diagnostic medical devices ◆ Procedura nadzoru rynkowego ⁶⁾ <input type="checkbox"/> Vigilance system procedure ◆ Inne <input type="checkbox"/> Other ◆ Inne <input type="checkbox"/> Other </div>	<div data-bbox="1087 235 1276 258">39.05.157, 1997-09-08</div> <div data-bbox="1087 288 1227 337">1242 5419 02.98 1242 6415 04.99</div> <div data-bbox="1087 678 1268 728">Q1Z 01 09 12974 243 2001-09-25</div>
Wszystkie załączone do wniosku dokumenty podlegają zwrotowi All documents enclosed to the application will be returned		
0012	Stwierdzam, że według mojej najlepszej wiedzy powyżej podane informacje są prawdziwe I affirm that the information given above is correct to best of my knowledge	
	<div data-bbox="277 1299 826 1374"> Miejscowość, data <u>Warszawa, dn. 13.05.2003</u> City, date </div> <div data-bbox="802 1299 1390 1453" style="text-align: right;"> Aesculap Chifa Spółka z ograniczoną odpowiedzialnością  Agata Wacowska-Jastrzebska Nazwisko i podpis Name and signature Specjalista ds. Marketingu i Rejestracji </div>	
1660	<div data-bbox="277 1546 1045 1694"> POTWIERDZENIE PRZYJĘCIA ZGŁOSZENIA O REJESTRACJĘ ¹⁾ Urząd Rejestracji Produktów Leczniczych Wyrobów Medycznych i Produktów Biobójczych ul. Chelmska 30/34, 00-725 Warszawa REGON 015249601 </div> <div data-bbox="695 1601 1390 1719" style="text-align: right;">  Gild Mawo Nazwisko i podpis osoby przyjmującej Data wpływu. ¹⁾ 2003-05-15 </div>	
0013	<div data-bbox="277 1750 652 2011"> POTWIERDZENIE WPISU DO REJESTRU ¹⁾  Pieczęć Urzędu </div> <div data-bbox="695 1750 1390 2011" style="text-align: right;"> Urząd Rejestracji Produktów Leczniczych Wyrobów Medycznych i Produktów Biobójczych PREZES  Prof. dr hab. med. Michał Pirożyński Nazwisko i podpis osoby upoważnionej 2003-06-03 Data ¹⁾ Pieczęć Urzędu </div>	

ORIGINAL

Zgłoszenie do rejestru wyrobu medycznego oznaczonego znakiem
zgodności CE, dla którego wystawiono deklarację zgodności

Form for the registration of the CE marked medical device placed on market

A.

1100	A. Dane organu kompetentnego / Identification of the Competent Authority Kod organu kompetentnego/ Code of competent authority ¹⁾		PL/CA 01
1110	Nazwa organu kompetentnego/ Name of competent authority ²⁾ Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych		
1120	Państwo/ Country ³⁾ Rzeczpospolita Polska PL	1130	Kraj związkowy / Federal Land ⁴⁾ —
1140	Miasto / City Warszawa	1150	Kod pocztowy / Postal code ⁶⁾ 00-725
1160	Ulica, nr domu, / Street, house no. ⁸⁾ Chełmska 30/34	1165	Skrytka poczt./ PO Box ⁹⁾ —
1190	Telefon/ Telephone no ¹¹⁾ 851 43 81	1180	Faks / Fax no ¹²⁾ 851 52 43
1200	B. Dane rejestracji / Identification of the registration 03.02.2003 Data rejestracji przez organ kompetentny ⁵⁾ ⁴⁾ Date of registration at competent authority ⁵⁾ ⁴⁾		
1210	Numer identyfikacyjny wytwórcy ⁶⁾ Registration no ⁶⁾ PL/CA01 00003		
1240	Określenie zgłaszającego/ Status of the organisation submitting the registration application <input type="checkbox"/> 01 Wytwórca/ Manufacturer ⁷⁾ <input checked="" type="checkbox"/> 02 Autoryzowany przedstawiciel/ Authorized representative		
1250	C. Dane wytwórcy/ Identification of the manufacturer ¹⁰⁾ ⁸⁾ Numer identyfikacyjny/ Manufacturer code ¹⁰⁾ ⁸⁾ DE 812160059		
1260	Pełna nazwa wytwórcy/ Name of manufacturer, full B.BRAUN MELSUNGEN AG		
1265	Nazwa wytwórcy skrócona/ Name of manufacturer, shortened ⁹⁾ B.BRAUN		
1270	Państwo / Country ³⁾ DE / NIEMCY	1280	Kraj związkowy / Federal Land ⁴⁾ Hesse
1290	Miasto / City MELSUNGEN	1300	Kod pocztowy / Postal code D-34212
1310	Ulica, nr domu, nr lokalu / Street, house no, apptmt CARL-BRAUN-STRASSE 1	1315	Skrytka poczt./ PO Box Postfach 11 20
1320	Osoba wskazana do kontaktu/ Contact person ¹²⁾ Dr Wilhelm Wucherpennig	1330	Numer telefonów / Telephone numbers +49 56 61 71 29 34
1340	Numer faksów / Fax numbers +49 56 61 75 29 34	1350	E-mail wilhelm.wucherpennig@bbraun.com

1360	D. Dane autoryzowanego przedstawiciela Identification of the authorized representative ¹⁰⁾		
	<input checked="" type="checkbox"/> 02 Autoryzowany przedstawiciel/ Authorized representative		
1370	Numer identyfikacyjny autoryzowanego przedstawiciela / Authorized representative code ¹⁰⁾ PL 788-00-08-829		
1380	Nazwa/ nazwisko autoryzowanego przedstawiciela / Name of the authorized representative, full AESCLAP CHIFA Sp. z o.o.		
1390	Państwo / Country ³⁾ POLSKA	0003	Kraj związkowy / Federal State ⁴⁾ ---
0001	Miasto /City NOWY TOMYŚL	0004	Kod pocztowy /Postal code 64-300
0002	Ulica, nr domu, nr lokalu / Street, house no, apartment no TYSIĄCLECIA 14	0005	Skrytka poczt/ PO Box ---
1400	Osoba wskazana do kontaktu / Contact person ¹²⁾ MAREK ŁUKASZYK	1410	Numerы telefonów / Telephone numbers (061) 44 20 290
1420	Numerы faksów / Fax numbers (061) 44 20 295	1430	E-mail marek.lukaszyk@chifa.com.pl
0006	<p>Czy wytwórca wymieniony w części C jest już zarejestrowany w Europejskim Obszarze Gospodarczym jako wytwórca wyrobów medycznych?/ Is described in box C manufacturer already registered within European Economic Area as medical devices manufacturer?</p> <p><input type="checkbox"/> nie/ no <input checked="" type="checkbox"/> tak/ yes Jeżeli „tak” proszę podać datę i numer rejestracji If „yes” please fill date and registration number</p> <p style="text-align: right; border: 1px solid black; padding: 5px;">Październik 1992 DE-CA 30/62</p> <p>Czy wytwórca wymieniony w części C ma zarejestrowanego w Europejskim Obszarze Gospodarczym autoryzowanego przedstawiciela?/ Has described in box C manufacturer, authorized representative within European Economic Area?</p> <p><input checked="" type="checkbox"/> nie/ no <input type="checkbox"/> tak/ yes Jeżeli „tak” proszę podać datę i numer rejestracji If „yes” please fill date and registration number</p>		
0007	<p>Stwierdzam, że według mojej najlepszej wiedzy powyżej podane informacje są prawdziwe I affirm that the information given above is correct to best of my knowledge</p> <p>Miejscowość, data <u>Warszawa, dn. 11.07.2003</u> City, date</p> <p style="text-align: right;"> Aesculap Chifa Spółka z ograniczoną odpowiedzialnością <i>Agata Wacowska-Jastrzębska</i> Specjalista ds. Marketingu i Rejestracji </p> <p style="text-align: right;">Nazwisko i podpis..... Name and signature</p>		

0009	Nazwa handlowa wyrobu, typ, wersje Product name, commercial name, product range, versions		Numer Rejestru Wytwórców i Wyrobów Medycznych Registration No of manufacturer & medical device
	Igły do znieczulania podpajęczynówkowego SPINOCAN® (według załącznika)	1210 0010	PL/CA01 00003 PL/DR 1) 001361
1220	Podać czy jest to pierwszy wpis do rejestru, zmiana wpisu, wykreślenie z rejestru <input checked="" type="checkbox"/> 01 Pierwsza rejestracja / First <input type="checkbox"/> 02 Zmiana rejestracji/ change ⁷⁾ <input type="checkbox"/> 03 Wykreślenie z rejestru/ withdrawn		
1230	W przypadku zmiany (02) lub wykreślenia z rejestru (03) podać poprzedni numer rejestru Previous registration number if registration changed (02) or withdrawn (03)		
1450	Nazwa techniczno-medyczna wyrobu według UMDNS (po polsku) ²⁾ Product generic name acc. to UMDNS (in Polish) Igły do znieczulania podpajęczynówkowego	1445	Kod UMDNS ²⁾ UMDNS Code
1460	Nazwa techniczno-medyczna wyrobu według UMDNS (po angielsku) ²⁾ Product generic name acc. to UMDNS (in English) Needles for spinal anaesthesia		
1480	Określenie kategorii wyrobu (po polsku) ³⁾ Product category description (in Polish) WYROBY JEDNORAZOWEGO UŻYCIA	1470	Kategoria wyrobu ³⁾ Product category 10
1490	Określenie kategorii wyrobu (po angielsku) ³⁾ Product category description (in English) SINGLE USE DEVICES		
1500	Krótki opis wyrobu medycznego i przewidziane przeznaczenie (po polsku) ⁴⁾ Short medical product description and intended use (in Polish) Igła SPINONOCAN® przeznaczona jest do znieczulania podpajęczynówkowego. Wyposażona w szlif Quincego, rowkowany uchwyt dla pewnego trzymania igły oraz przezroczystą końcówkę lock. Mandryn oznaczony kolorami. Jałowa, wyłącznie jednorazowego użytku.		
1510	Krótki opis wyrobu medycznego i przewidziane przeznaczenie (po angielsku) ⁴⁾ Short medical product description and intended use (in English) SPINOCAN® needle for spinal anaesthesia. Equipped with Quincke bevel, ergonomic hub design, transparent lock hub. Colour-coded stylet hub. Sterile, single use only.		
1520	Klasyfikacja/Classification Nr Jedn. Notyfikowanej Notified Body ID <input type="checkbox"/> Klasa I reguła..... ⁵⁾ Class I rule <input type="checkbox"/> Klasy I sterylne ⁵⁾ Class I sterile <input type="checkbox"/> Klasy I z funkc. pomiar. ⁵⁾ Class I with measuring function	1530	Klasyfikacja / Classification Nr Jedn. Notyfikowanej Notified Body ID <input checked="" type="checkbox"/> Klasa IIa reguła....6..... ¹⁸⁾ 0123 Class IIa rule no <input type="checkbox"/> Klasa IIb reguła ¹⁸⁾ Class IIb rule no <input type="checkbox"/> Klasa III reguła..... ¹⁸⁾ Class III rule no
1525	Wyrób do diagnostyki in vitro z wyjątkiem wyrobu przeznaczonego do oceny działania In vitro diagnostic device <input type="checkbox"/> Lista A ⁵⁾ List A <input type="checkbox"/> Lista B ¹⁸⁾ <input type="checkbox"/> Do samodzielnego testowania List B Self testing IVD <input type="checkbox"/> Nie klasyfikowany do listy A albo B non-classified to list A or B ⁵⁾	1535	<input type="checkbox"/> Wyposażenie wyrobu medycznego ⁵⁾ Accessory for the medical device -----
		1550	<input type="checkbox"/> System lub zestaw zabiegowy ⁵⁾ System or procedure pack -----
1580	Opis systemu lub zestawu zabiegowego ⁵⁾ Description of system or procedure pack -----		



0011

Dokumenty dołączone do wniosku (zakreślić jeżeli są)
Documents enclosed to the application (cross box if yes)

Oznaczenia i daty załączników
Codes and dates of annexes

◆ Deklaracja zgodności Declaration of conformity	<input checked="" type="checkbox"/>	39.05.155, 1997-09-08
◆ Instrukcja używania, etykiety i ulotka informacyjna ⁶⁾ User's manual and labels	<input checked="" type="checkbox"/>	B.01,5.05.98/2 Nr 604 0039 B.07,5.02.99/1 Nr 604 0004
◆ Opis wyrobu ⁶⁾	<input type="checkbox"/>	
◆ Product descriptions		
◆ Opis procesu produkcji ⁶⁾	<input type="checkbox"/>	
◆ Production process description		
◆ Ocena kliniczna lub ocena działania ⁶⁾ Clinical evaluation	<input type="checkbox"/>	
◆ Protokoły badań ⁶⁾ Test reports	<input type="checkbox"/>	
◆ Wyniki analizy ryzyka ⁶⁾ Risk analysis results	<input type="checkbox"/>	
◆ Analiza zgodności z wymaganiami zasadniczymi ⁶⁾ Essential requirements conformity analysis	<input type="checkbox"/>	
◆ Certyfikat systemu jakości ⁶⁾ Certificate of quality system	<input checked="" type="checkbox"/>	Q1Z 02 08 12974 251 2002-08-28
◆ Certyfikat oceny typu wyrobu ⁶⁾ ⁷⁾ Certificate of type examination	<input type="checkbox"/>	
◆ Opis procesu sterylizacji ⁶⁾ ⁷⁾ Sterilisation process description	<input type="checkbox"/>	
◆ Certyfikat parametrów pomiarowych ⁶⁾ ⁷⁾ Measurement characteristics certificate	<input type="checkbox"/>	
◆ Informacje wymagane dla wyrobów do diagnostyki in vitro ⁷⁾ Information required for in vitro diagnostic medical devices	<input type="checkbox"/>	
◆ Procedura nadzoru rynkowego ⁶⁾ Vigilance system procedure	<input type="checkbox"/>	
◆ Inne: Autoryzacja, Załącznik do wniosku, Certyfikat CE, potwierdzenie dokonania opłaty rejestracyjnej Other	<input checked="" type="checkbox"/>	Autoryzacja: HC-RA-DE08S 2003-04-01 Certyfikat CE: G1 02 08 12974 250 2002-08-28 Opłata: 2003-06-11

Wszystkie załączone do wniosku dokumenty podlegają zwrotowi
All documents enclosed to the application will be returned

0012

Stwierdzam, że według mojej najlepszej wiedzy powyżej podane informacje są prawdziwe
I affirm that the information given above is correct to best of my knowledge

Miejscowość, data Warszawa, dn. 11.07.2003
City, date

Nazwisko i podpis
Name and signature

Aesculap Chifa
Spółka z ograniczoną odpowiedzialnością

Agata Wacowska-Jastrzebska
Specjalista ds. Marketingu i Rejestracji

1560

POTWIERDZENIE PRZYJĘCIA ZGŁOSZENIA O REJESTRACJĘ ¹⁾

Urząd Rejestracji Produktów Leczniczych
Wyrobow Medycznych i Produktów Biobójczych
ul. Chełmska 30/34, 00-725 Warszawa
REGON: 145240601

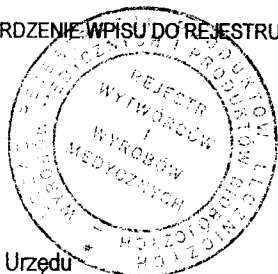
Pieczęć Urzędu

Data wpływu ¹⁾

2003 -07- 16

0013

POTWIERDZENIE WPISU DO REJESTRU ¹⁾



Pieczęć Urzędu

Nazwisko i podpis osoby upoważnionej

Urząd Rejestracji Produktów Leczniczych
Wyrobow Medycznych i Produktów Biobójczych
z up. Prezesa

dr inż. Marian Nowicki

Data ¹⁾

28.08.2003

Załącznik do zgłoszenia do rejestru igły do znieczulania podpajęczynówkowego SPINOCAN® z prowadnicą

Agata Wacowska-Jastrzębska
Specjalista ds. Marketingu i Rejestracji

Strona 1 z 2

Lista produktów

Nr kat.	Opis
4505913	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 25
4505905	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 25
4509757	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 20
4506090	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 22
4501900	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 29, z prowadnicą
4505751	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 25
4507908	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 22
4507754	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 22
4507401	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 22
4509900	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 20
4502906	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 26, z prowadnicą
4509200	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 20
4503902	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 27, z prowadnicą
4504917	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 26
4501195	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 19
4501144	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 19
4501390	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 18
4501373	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 18
4501918	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 29
4502140	Spinocan [®] , igła do znieczulania podpajęczynówkowego, G 27
4505000	Prowadnica do Spinocan [®] , G 20
4500059	Prowadnica do Spinocan [®] , G 22
4500105	Prowadnica do Spinocan [®] , G 20

Aesculap Chifa
Spółka z ograniczoną odpowiedzialnością
Agata Wacowska-Jastrzębska
Specjalista ds. Marketingu i Rejestracji

Wdrożenia i Usługi Techniczne,
Wyrobów Medycznych i Produktów
Biobójczych
ul. Chelmska 30/34, 00-725 Warszawa
REGON 015249601

MANUFACTURER'S DECLARATION

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	B. Braun Melsungen AG
Manufacturer address and contact details	Carl-Braun Straße 1 34212 Melsungen GERMANY
Single Registration Number (SRN) (if available)	DE-MF-000000201

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Notified body name (if applicable)	TÜV SÜD Product Service GmbH	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	0123	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	(1) G1 012974 0607; (2) G1 019717 0032; (3) G1 022239 0080; (4) G2S 012974 0457	<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	(1) 2024-05-26; (2) 2024-05-26; (3) 2024-05-26; (4) 2024-05-26	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	2028-12-31	<input checked="" type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above or in the attached schedule
- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- ☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- ☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Quality Management System (QMS)

Choose one applicable statement:

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

➤ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

	Quality Management	Regulatory Affairs
Full Company Name	B. Braun Melsungen AG	B. Braun Melsungen AG
Location & Date	Melsungen, 2024-04-15	Melsungen, 2024-04-15
Signature	See electronic signature	See electronic signature
Print Name	(1) Thomas Brand; (2) Mareike Arico; (3) Dr. Frank Ritz	(4) Dr. Stefan Seidel; (5) Malte Loh; (6) Dr. Joachim Buenger
Title	(1) Vice President Quality Management for non-active Medical Devices; (2) Head of Quality Management Active Medical Devices/ Head of	(4) Head of Regulatory Affairs CoE Infusion & Pain Therapy; (5) Senior Manager Regulatory



	Regulatory Affairs CoE AIS; (3) Vice President QM Pharma; Hospital Care Division	Affairs; (6) Director Template & Submission Mgmt
Contact Details (at least email)	BBMAG-HC@bbraun.com	BBMAG-HC@bbraun.com
Version of document	Version 1.0	

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

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

Schedule of Devices

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

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)			Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Perfusor® compactplus	8717030	4039239000000038ZM	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus	8717050	40392390000005352B	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
OnlineSuite	876100	40392390000005552H	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Perfusor®	8719030	40392390000007562V	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Infusomat®	8719050	40392390000007552T	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus P	8717070	40392390000007492Y	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4116011F	4039239000000039ZP	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617006	4039239000000044ZG	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	932M04SE	403923900000018743B	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	931M08SE		NB0123					N/A
Drainobag® 600 V	5523606	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drug Library Manager Spaceplus	876203	403923900000169539	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drug Library Manager Spaceplus	876209	403923900000169539	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FR29914	403923900000249638	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FREU914							N/A
GLYCINE 1,5 % B. BRAUN	FREU934							N/A
GLYCINE 1,5 % B. BRAUN	FREU954							N/A
GLYCINE 1,5 % B. BRAUN	FREU974							N/A
NaCl 0,9 % B. BRAUN	FREU850	403923900000250128	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	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	40392390000026312N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	3637006							N/A
NaCl 0,9 % B. BRAUN	0069414E							N/A
NaCl 0,9 % B. BRAUN	3521360							N/A
NaCl 0,9 % B. BRAUN	3570120							N/A

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

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

Schedule of Devices

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

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)			Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
NaCl 0,9 % B. BRAUN	3570130							N/A
NaCl 0,9 % B. BRAUN	3570140							N/A
NaCl 0,9 % B. BRAUN	0066570E							N/A
NaCl 0,9 % B. BRAUN	3521370							N/A
NaCl 0,9 % B. BRAUN	3570150							N/A
NaCl 0,9 % B. BRAUN	3570160							N/A
NaCl 0,9 % B. BRAUN	3570170							N/A
NaCl 0,9 % B. BRAUN	0066569E							N/A
NaCl 0,9 % B. BRAUN	3570110							N/A
Vitulia	450268	40392390000025022A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
NaCl 0,9 % B. BRAUN	3570370							N/A
NaCl 0,9 % B. BRAUN	3570380							N/A
NaCl 0,9 % B. BRAUN	3570390							N/A
NaCl 0,9 % B. BRAUN	391860							N/A
NaCl 0,9 % B. BRAUN	3570410							N/A
NaCl 0,9 % B. BRAUN	3570420							N/A
NaCl 0,9 % B. BRAUN	3570460	40392390000026302L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	3570470		NB0123					N/A
NaCl 0,9 % B. BRAUN	3570480							N/A
RINGER B. BRAUN	FREU864	40392390000025062J	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	FREU924		NB0123					FREU920
RINGER B. BRAUN	FREU944							N/A
RINGER B. BRAUN	FREU964							N/A
RINGER B. BRAUN	FREU984							N/A
RINGER B. BRAUN	3570000	40392390000026342U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	3570010		NB0123					N/A
RINGER B. BRAUN	3570020							N/A
RINGER B. BRAUN	3570030							N/A
RINGER B. BRAUN	3570040							N/A
RINGER B. BRAUN	3570050							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
RINGER B. BRAUN	3570060							N/A
RINGER B. BRAUN	3570611	40392390000026322Q	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570490
RINGER B. BRAUN	3570610							3570500
RINGER B. BRAUN	3570614							3570510
RINGER B. BRAUN	3570612							3570520
RINGER B. BRAUN	3570613	40392390000026332S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570530
Aqua B. Braun	FREU812	40392390000024973A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	FREU852							N/A
Aqua B. Braun	FREU912							N/A
Aqua B. Braun	FREU932							N/A
Aqua B. Braun	387872	40392390000026272X	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	387873		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Aqua B. Braun	387874							N/A
Aqua B. Braun	442464							N/A
Aqua B. Braun	442465							N/A
Aqua B. Braun	442466							N/A
Sterile Water for Irrigation	3637011							N/A
Aqua B. Braun	3521380	403923900000262933	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	3521390							N/A
Aqua B. Braun	3553949							N/A
Aqua B. Braun	3553957							N/A
Aqua B. Braun	0065729E							N/A
Aqua B. Braun	0066571E							N/A
Aqua B. Braun	0069415E							N/A
Aqua B. Braun	0082423E							N/A
Aqua B. Braun	0082479E							N/A
Sterile Water for Irrigation	3637007							N/A
Perifix® Catheter Connector	4513800	403923900000238732	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Catheter Connector	4513801							N/A
Perifix® Catheter Connector NRFit	4513800N-01							N/A
Perifix® Catheter Connector NRFit	4513801N-01							N/A
Infusomat® Space	8713050	40392390000007462S	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Space P	8713070	40392390000007472U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Perfusor® Space	8713030	40392390000007482W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Enteroport® plus	8710355	40392390000007452Q	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200	40392390000008622V	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200-20							N/A
Infusomat® Plus Line SafeSet	8700210							N/A
Infusomat® Plus Line	8700310							N/A
Infusomat® Plus Line	8700310-20							N/A
Infusomat® Plus Line	8700310CN							N/A
Cyto-Set® Infusomat® Space	8250414SP	40392390000007832Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set® Infusomat® Space	835414SP							N/A
Cyto-Set® Infusomat® Space	835817SP							N/A
Cyto-Set® Infusomat® Space	835820SP							N/A
Cyto-Set® Infusomat® Space	835917SP							N/A
Cyto-Set® Infusomat® Space	835920SP							N/A
Cyto-Set® Infusomat® plus	8700420							N/A
Cyto-Set® Infusomat® plus	8700430							N/A
Cyto-Set® Infusomat® plus	8700440							N/A
Cyto-Set® Infusomat® plus	8700450							N/A
Cyto-Set® Infusomat® plus	8700460							N/A
Cyto-Set® Infusomat® plus	8700470							N/A
Cyto-Set® Infusomat® plus	8700480							N/A
Cyto-Set® Infusomat® plus	8700490							N/A
Cyto-Set® Line	A2581NF	403923900000078432	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Line	A2582NF		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set® Mix	A2900N							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	4039239000008602R	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® A	4894539							N/A
Stimuplex® A	4894367							N/A
Stimuplex® A	4894502							N/A
Stimuplex® A	4894375							N/A
Stimuplex® A	4894260							N/A
Stimuplex® A	4894278							N/A
Stimuplex® A	4894278NR							N/A
Stimuplex® A	4894375NR							N/A
Stimuplex® A	4894260NR							N/A
Stimuplex® A	4894367NR							N/A
Stimuplex® A	4894539NR							N/A
Stimuplex® A	4894502NR							N/A
Stimuplex® A	4894251 NR							N/A
Easypump® II LT 60-12	4540002	40392390000023452J	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Easypump® II LT 60-12	4540002-07							N/A
Easypump® II LT 60-12	4540002-20							N/A
Easypump® II LT 500-12.5	4540003							N/A
Easypump® II LT 500-12.5	4540003-07							N/A
Easypump® II LT 500-12.5	4540003-20							N/A
Easypump® II LT 80-16	4540004							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II LT 80-16	4540004-07							N/A
Easypump® II LT 80-16	4540004-20							N/A
Easypump® II LT 125-25	4540006							N/A
Easypump® II LT 125-25	4540006-07							N/A
Easypump® II LT 125-25	4540006-20							N/A
Easypump® II LT 270-27	4540008							N/A
Easypump® II LT 270-27	4540008-07							N/A
Easypump® II LT 270-27	4540008-20							N/A
Easypump® II LT 60-30	4540010							N/A
Easypump® II LT 60-30	4540010-07							N/A
Easypump® II LT 60-30	4540010-20							N/A
Easypump® II LT 120-30	4540012							N/A
Easypump® II LT 120-30	4540012-07							N/A
Easypump® II LT 120-30	4540012-20							N/A
Easypump® II LT 400-40	4540014							N/A
Easypump® II LT 400-40	4540014-07							N/A
Easypump® II LT 400-40	4540014-20							N/A
Easypump® II LT 100-50	4540016							N/A
Easypump® II LT 100-50	4540016-07							N/A
Easypump® II LT 100-50	4540016-20							N/A
Easypump® II LT 270-54	4540018							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II LT 270-54	4540018-07							N/A
Easypump® II LT 270-54	4540018-20							N/A
Easypump® II LT 400-80	4540022							N/A
Easypump® II LT 400-80	4540022-07							N/A
Easypump® II LT 400-80	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II ST 50-1	4540044-07							N/A
Easypump® II ST 50-1	4540044-20							N/A
Easypump® II ST 100-1	4540046							N/A
Easypump® II ST 100-1	4540046-07							N/A
Easypump® II ST 100-1	4540046-20							N/A
Easypump® II ST 250-1	4540048							N/A
Easypump® II ST 250-1	4540048-07							N/A
Easypump® II ST 250-1	4540048-20							N/A
Easypump® II ST 250-1,5	4540050							N/A
Easypump® II ST 250-1,5	4540050-07							N/A
Easypump® II ST 250-1,5	4540050-20							N/A
Easypump® II ST 400-2	4540052							N/A
Easypump® II ST 400-2	4540052-07							N/A
Easypump® II ST 400-2	4540052-20							N/A
Easypump® II ST 500-2	4540054							N/A
Easypump® II ST 500-2	4540054-07							N/A
Easypump® II ST 500-2	4540054-20							N/A
Easypump® II ST 100-2	4540056							N/A
Easypump® II ST 100-2	4540056-07							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000085836	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	4505000
Spinal Introducer	4500059-13		NB0123					4500059
Contiplex® S 360	4898650CN	40392390000008542W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® S 360	4898610CN		NB0123					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	403923900000238834	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Filter NRFit	4515501N-01		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® S Ultra 360® NRFit®	4898650NR-27	40392390000008542W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® S Ultra 360® NRFit®	4898610NR-27							N/A
Contiplex® S Ultra 360® NRFit®	4898615NR-27							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898704NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898705NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898710NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898715NR-01							N/A
Contiplex® Tuohy Ultra 360®	4898704-01							N/A
Contiplex® Tuohy Ultra 360®	4898705-01							N/A
Contiplex® Tuohy Ultra 360®	4898710-01							N/A
Contiplex® Tuohy Ultra 360®	4898715-01							N/A
Contiplex® Tuohy Ultra 360®	4898704-27							N/A
Contiplex® Tuohy Ultra 360®	4898705-27							N/A
Contiplex® Tuohy Ultra 360®	4898710-27							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® Tuohy Ultra 360®	4898715-27							N/A
Discofix®	4099117	40392390000007582Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix®	4095111		NB0123					N/A
Discofix®	4095120							N/A
Discofix®	4095146							N/A
Discofix®	4095111IN							N/A
Discofix®	409511CN							N/A
Discofix®	409512CN							N/A
Discofix®	16466							N/A
Discofix®	4098102							N/A
Discofix®	409810CN							N/A
Discofix®	4098218							N/A
Discofix®	409821CN							N/A
Discofix®	4098501							N/A
Discofix®	4098234							N/A
Discofix®	4098080							N/A
Discofix®	4055150							N/A
Discofix®	4055145							N/A
Discofix®	4055146							N/A
Discofix®	4055149							N/A
Discofix®	4055147							N/A
Discofix®	4055148							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix®	4099010							N/A
Discofix®	4095210							15809
Nutritub® ENFit® intestinal	9246605	40392390000029463J	G1 019717 0032 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246584
Nutritub® ENFit® intestinal	9246604		B. Braun Avitum Italy S.p.A.					9246586
Nutritub® ENFit® intestinal	9246604							9246576
Nutritub® ENFit® intestinal	9246604							9246578
Nutritub® Gastral Basic ENFit®	9246603	40392390000008172Q	G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246519
Nutritub® Gastral Basic ENFit®	9246602		NB0123					9246518
Nutritub® Gastral Basic ENFit®	9246601		B. Braun Avitum Italy S.p.A.					9246516
Nutritub® Gastral Basic ENFit®	9246600							9246550
Nutritub® Gastral Basic ENFit®	9246599							9246515
Nutritub® Gastral Basic ENFit®	9246598							9246592
Nutritub® Gastral Basic ENFit®	9246597							9246514
Nutritub® Gastral Basic ENFit®	9246597							9246513
Nutritub® Gastral Basic ENFit®	9246597							9246541
Nutritub® Gastral Basic ENFit®	9246597							9246543

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
			NB0123					
Pleurofix® No. 1	4461002	40392390000007902V	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleurofix® No. 2	4461037		NB0123					N/A
Seldinger Introducer Needle	4206096	40392390000007442N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Seldinger Introducer Needle	4206100		NB0123					N/A
Injekt® 40 Duo	9166432C	4039239000000121823	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® 40 Duo	9166432V		NB0123					N/A
Introcan Safety® 3	4251127-01	40392390000007652W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety® 3	4251127-03		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Introcan Safety® 3	4251134-01							N/A
Introcan Safety® 3	4251134-03							N/A
Introcan Safety® 3	4251134-04							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Infusomat® Space Line	8700036SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line	8700435SP							N/A
Infusomat® Space Line SafeSet	8701148SP							N/A
Infusomat® Space Line	8270066SP-01	403923900000086635	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8270066SP
Infusomat® Space Line	8270066SP-26							N/A
Infusomat® Plus Line	8700350-01	403923900000086533	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-26							N/A
Enteroport® ENFit® Set		4039239000000263732	G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8721748

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set®	8250266	40392390000007832Y	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set®	8250366							N/A
ProSet Cyto-Set®	8250370							N/A
ProSet Cyto-Set® 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

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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set® Mix	4188925							N/A
ProSet Cyto-Set® Mix	4188926							N/A
ProSet Cyto-Set® Pump Adapter	4182704	403923900000078534	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Pump Adapter	A1673SO		NB0123					N/A
Dosifix®	4037011	40392390000008192U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Dosifix®	4037012		NB0123					N/A
Dosifix®	4037013							N/A
Dosifix®	4037032							N/A
Dosifix®	4037031	40392390000008202D	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					
Heidelberger Extension Tubing	4033809	403923900000078636	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4034589		NB0123					N/A
Heidelberger Extension Tubing	4038703							N/A
Heidelberger Extension Tubing	4055128							N/A
Heidelberger Extension Tubing	4055136							N/A
Extension Line, Type: Heidelberg	4097130							N/A
Extension Line, Type: Heidelberg	4097173							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Introcan® Certo	4055764	40392390000007612N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan® Certo	4251300							N/A
Introcan® Certo	4251318							N/A
Introcan® Certo	4251326							N/A
Introcan® Certo	4251334							N/A
Introcan® Certo	4251342							N/A
Introcan® Certo	4251350							N/A
Introcan® Certo	4251369							N/A
Introcan®	4252071B							N/A
Introcan®	4252098B							N/A
Introcan®	4252110B							N/A
Introcan®	4252136B							N/A
Introcan®	4252160B							N/A
Introcan®	4252217B							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan®	4252322B							N/A
Introcan®-W Certo	4253302							N/A
Introcan®-W Certo	4253310							N/A
Introcan®-W Certo	4253329							N/A
Introcan®-W Certo	4253337							N/A
Introcan®-W Certo	4253345							N/A
Introcan®-W Certo	4253353							N/A
Introcan®-W Certo	4253361							N/A
Introcan®-W	4254074B							N/A
Introcan®-W	4254090B							N/A
Introcan®-W	4254112B							N/A
Introcan®-W	4254139B							N/A
Introcan®-W	4254171B							N/A
Introcan®-W	4254210B							N/A
Introcan®-W	4254325B							N/A
Discofix® C Safeflow	16494CCN	40392390000007602L	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C Safeflow	16495CCN							N/A
Discofix® C Safeflow	16501CCN							N/A
Discofix® C Safeflow	16500CCN							N/A
Discofix® C Safeflow	16540CCN							N/A
Discofix® C Safeflow	16520CCN							N/A
Intrapur®-Neonat	4099451	40392390000008082P	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrapur®	4093216							N/A
Sterifix®	4184637							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000075933	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16540C							N/A
Discofix® C	16494C							N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix® C	16720C							N/A
Discofix® C	16520CSF							N/A
Discofix® C	16520C							N/A
Discofix® C	16701C							N/A
Discofix® C	16496C							N/A
Discofix® C	16501CSF-1							N/A
Discofix® C	RU16496C							N/A
Discofix® C	RU16495C							N/A
Discofix® C	CN16496C							N/A
Discofix® C	RU16494C							N/A
Discofix® C	EC16494C							N/A
Discofix® C	CN16494C							N/A
Discofix® C	16611C							N/A
Discofix® C	16608C							N/A
Discofix® C	16600C							N/A
Discofix® C	16501CSF							N/A
Pleuracan®	4462556	40392390000007922Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleuracan® B	4462505		NB0123					N/A
Pleuracan® Back-Check Valve	4462564	403923900000079333	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600	5523682	4039239000000281736	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16700C	403923900000075933	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16500C		NB0123					N/A
Discofix® C	16495C							N/A
Discofix® C	16560CSF							N/A
Discofix® C	16901C							N/A
Discofix® C	16615C							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000026953G	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4052197							N/A
Heidelberger Extension Tubing	4052197H							N/A
Introcan Safety®	4251601-01	40392390000007632S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety®	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan Safety®	4252519-03							N/A
Introcan Safety®	4252519-04							N/A
Introcan Safety®	4252520-01							N/A
Introcan Safety®	4252527-01							N/A
Introcan Safety®	4252527-03							N/A
Introcan Safety®	4252535-01							N/A
Introcan Safety®	4252535-03							N/A
Introcan Safety®	4252535-04							N/A
Introcan Safety®	4252543-01							N/A
Introcan Safety®	4252551-01							N/A
Introcan Safety®	4252551-03							N/A
Introcan Safety®	4252551-04							N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan Safety® W	4253604-01							N/A
Introcan Safety® W	4253604-03							N/A
Introcan Safety® W	4253604-04							N/A
Introcan Safety® W	4253604JP							N/A
Introcan Safety® W	4253612-01							N/A
Introcan Safety® W	4253612-03							N/A
Introcan Safety® W	4253612-04							N/A
Introcan Safety® W	4253639-01							N/A
Introcan Safety® W	4253639-03							N/A
Introcan Safety® W	4253639JP							N/A
Introcan Safety® W	4253639-04							N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000008082P	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Intrapur®	4183925							N/A
ProSet Intrapur®	4183926							N/A
ProSet Intrapur®	4183927							N/A
ProSet Intrapur®	4183948							N/A
ProSet Intrapur®	4183949							N/A
ProSet Intrapur®	4184004							N/A
ProSet Intrapur®	4184006							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Intrapur®	4184007							N/A
ProSet Intrapur®	4184008							N/A
ProSet Intrapur®	4098725							N/A
ProSet Intrapur®	4081002							N/A
ProSet Sterifix® Neonat	4099265							N/A
ProSet Intrapur®	4187822							N/A
ProSet Intrapur®	4184001							N/A
ProSet Intrapur®	4183255							N/A
ProSet Intrapur®	4183245							N/A
ProSet Intrapur®	4183240							N/A
ProSet Intrapur®	4180351							N/A
ProSet Intrapur®	4180350							N/A
ProSet Discofix® C	4188960	403923900000075933	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Discofix® C	4188959							N/A
ProSet Discofix® C	4188957							N/A
ProSet Discofix® C	4188105							N/A
ProSet Discofix® C	4188071							N/A
ProSet Discofix® C	4187954							N/A
ProSet Discofix® C	4187826							N/A
ProSet Discofix® C	4187202							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4187199							N/A
ProSet Discofix® C	4187032							N/A
ProSet Discofix® C	4184963							N/A
ProSet Discofix® C	4184491							N/A
ProSet Discofix® C	4184246							N/A
ProSet Discofix® C	4184030							N/A
ProSet Discofix® C	4184022							N/A
ProSet Discofix® C	4182635							N/A
ProSet Discofix® C	4181234							N/A
ProSet Discofix® C	4180965							N/A
ProSet Discofix® C	4086481							N/A
ProSet Discofix® C	4085230							N/A
ProSet Discofix® C	4085213							N/A
ProSet Discofix® C	4187203							N/A
ProSet Discofix® C	4182308							N/A
ProSet Discofix® C	4187527							N/A
ProSet Discofix® C	4180437							N/A
ProSet Discofix® C	4183088							N/A
ProSet Discofix® C	4088698							N/A
ProSet Discofix® C	4084792							N/A
ProSet Discofix® C	4085300SF							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4085086							N/A
ProSet Discofix® C	4181027							N/A
ProSet Discofix® C	4184005							N/A
ProSet Discofix® C	4187291							N/A
ProSet Discofix® C	4183312							N/A
ProSet Discofix® C	4185366							N/A
ProSet Discofix® C	4185927							N/A
ProSet Discofix® C	4188188							N/A
ProSet Discofix® C	4086482							N/A
ProSet Discofix® C	4184327							N/A
ProSet Discofix® C	4180439							N/A
ProSet Discofix® C	4180306							N/A
ProSet Discofix® C	4182944							N/A
ProSet Discofix® C	4083255							N/A
ProSet Discofix® C	4187911							N/A
ProSet Discofix® C	4187823							N/A
ProSet Discofix® C	4187878							N/A
ProSet Discofix® C	4085168							N/A
ProSet Discofix® C	4189821							N/A
ProSet Discofix® C	4188958							N/A
ProSet Discofix® C	4187213							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4187880							N/A
ProSet Discofix® C	4083254							N/A
ProSet Discofix® C	4189847							N/A
ProSet Discofix® C	4188198							N/A
ProSet Discofix® C	4183510							N/A
ProSet Discofix® C	4187033							N/A
ProSet Discofix® C	4188072							N/A
ProSet Discofix® C	4183787							N/A
ProSet Discofix® C	4180678							N/A
ProSet Discofix® C	4180679							N/A
ProSet Discofix® C	4187879							N/A
ProSet Discofix® C	4185928							N/A
ProSet Discofix® C	4086879							N/A
ProSet Discofix® C	4188047							N/A
ProSet Discofix® C	4189839							N/A
ProSet Discofix® C	4183852							N/A
ProSet Discofix® C	4185985							N/A
ProSet Discofix® C	4085450SF							N/A
ProSet Discofix® C	4089464							N/A
ProSet Discofix® C	4182737							N/A
ProSet Discofix® C	4180300							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4183777							N/A
ProSet Discofix® C	4185972							N/A
ProSet Discofix® C	4184521							N/A
ProSet Discofix® C	4182652							N/A
ProSet Discofix® C	4184483							N/A
ProSet Discofix® C	4087930							N/A
ProSet Discofix® C	4184817							N/A
ProSet Discofix® C	4187391							N/A
ProSet Discofix® C	4182720							N/A
ProSet Discofix® C	4185821N							N/A
ProSet Discofix® C	4085434SF							N/A
ProSet Discofix® C	4188225							N/A
ProSet Discofix® C	4186580							N/A
ProSet Discofix® C	4186579							N/A
ProSet Discofix® C	4085500SF							N/A
ProSet Discofix® C	4181778							N/A
ProSet Discofix® C	4180459							N/A
ProSet Discofix® C	4188510							N/A
ProSet Discofix® C	4180438							N/A
ProSet Discofix® C	4086945							N/A
ProSet Discofix® C	4187898							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4185021							N/A
ProSet Discofix® C	4187529							N/A
ProSet Discofix® C	4088520							N/A
ProSet Discofix® C	4181028							N/A
ProSet Discofix® C	4182638							N/A
ProSet Discofix® C	4088699							N/A
ProSet Discofix® C	4180120							N/A
ProSet Discofix® C	4180677							N/A
ProSet Discofix® C	4182633							N/A
ProSet Discofix® C	4182639							N/A
ProSet Discofix® C	4187838							N/A
ProSet Discofix® C	4084510							N/A
ProSet Discofix® C	4182651							N/A
ProSet Discofix® C	4187834							N/A
ProSet Discofix® C	4180445							N/A
ProSet Discofix® C	4083777							N/A
ProSet Discofix® C	4187308							N/A
ProSet Discofix® C	4184424							N/A
ProSet Discofix® C	4182182							N/A
Vasofix® Braunüle®	4268091B	40392390000007622Q	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasofix® Braunüle®	4268113B		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasofix® Braunüle®	4268130B							N/A
Vasofix® Braunüle®	4268156B							N/A
Vasofix® Braunüle®	4268172B							N/A
Vasofix® Braunüle®	4268210B							N/A
Vasofix® Braunüle®	4268334B							N/A
Vasofix® Certo	4269071							N/A
Vasofix® Certo	4269098							N/A
Vasofix® Certo	4269110							N/A
Vasofix® Certo	4269136							N/A
Vasofix® Certo	4269152							N/A
Vasofix® Certo	4269179							N/A
Vasofix® Certo	4269217							N/A
Vasofix® Certo	4269225							N/A
Vasofix® Certo	4269330							N/A
Extension Line	4051807							40392390000007893C
Extension Line	4054393	NB0123	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						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000007642U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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
Vasofix® Safety	4268210S-03							N/A
Vasofix® Safety	4268334S-01							N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasofix® Safety	4269179S-03							N/A
Vasofix® Safety	4269179SIN							N/A
Vasofix® Safety	4269179S-20							N/A
Vasofix® Safety	4269217S-01							N/A
Vasofix® Safety	4269217S-03							N/A
Vasofix® Safety	4269217S-20							N/A
Vasofix® Safety	4269225S-01							N/A
Vasofix® Safety	4269225S-03							N/A
Vasofix® Safety	4269225S-20							N/A
Vasofix® Safety	4269330S-01							N/A
Vasofix® Safety	4269330S-03							N/A
Vasofix® Safety	4269330S-20							N/A
ProSet Spiral Line	4091728	40392390000007893C	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Spiral Line	4091736							N/A
ProSet Spiral Line	4091740							N/A
ProSet Spiral Line	4091752							N/A
ProSet Spiral Line	4092539							N/A
ProSet Spiral Line	4092937							N/A
ProSet Spiral Line	4092945							N/A
ProSet Spiral Line	4092953							N/A
ProSet Spiral Line	4092961							N/A

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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Extension Line	4095251							N/A
ProSet Extension Line	4097531							N/A
Extension Line	4097572							N/A
ProSet Spiral Line	4099362							N/A
ProSet Extension Line	4185841							N/A
ProSet Extension Line	4185842							N/A
ProSet Spiral Line	4187466							N/A
ProSet Spiral Line	4187467							N/A
ProSet Spiral Line	4187468							N/A
ProSet Spiral Line	4187469							N/A
ProSet Spiral Line	4188080							N/A
Extension Line	9500049							N/A
Extension Line	9500057							N/A
Extension Line	9500065							N/A
Infusomat@plus Line SafeSet	8700390	40392390000014782X	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat@plus Line SafeSet	8700391		NB0123					N/A
Infusomat@plus Line SafeSet	8700392	403923900000259235	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Space Line SafeSet	8700140SP	40392390000014772V	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line SafeSet	8700141SP		NB0123					N/A
Infusomat® Space Line SafeSet	8700142SP	403923900000259133	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4060369L	40392390000007812U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4060407		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® SafeSet	4063005							N/A
Intrafix® SafeSet	4063006							N/A
Drainobag® Basse Pression	5524237	403923900000281736	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 300	5522390							N/A
Drainobag® 150	5523753							N/A
Drainobag® Lock 150	5523761							N/A
Drainobag® Lock 150	55237611							N/A
Drainobag® Lock 400	5523602							U2000600
Drainobag® 600 V	5523605							N/A
Drainobag® Lock 600 V	5523648	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 V	5523649							N/A
Drainobag® Basse Pression TL	5524210							N/A
Drainobag® 300 V	5522322							N/A
Drainobag® Lock 300 V	5522340							N/A
Drainobag® Lock 300 V	55223401							N/A
Drainobag® 150 V	5523702							N/A
Drainobag® 150 VL	5523710							N/A
Drainobag® Lock 150 V	5523729							N/A
Drainobag® Lock 150 VL	5523737							N/A
Drainobag® Lock 150 VL	55237371							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drainobag® 400 V	5523601							U2000500
Drainobag® Lock 400 V	5523603							U2000700
Drainobag® Lock 600 K 10	5523400	40392390000028193A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 K 10	5523401							N/A
Drainobag® Lock 600 K 12	5523427							N/A
Drainobag® Lock 600 K 12	5523428							N/A
Intrafix® SafeSet	4063144	40392390000007812U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4063148							N/A
Intrafix® Primeline	4063287							N/A
ProSet Intrafix® Primeline	4088549							N/A
Intrafix® SafeSet	4110000							N/A
Intrafix® SafeSet	4110010							N/A
ProSet Intrafix® Primeline	4180038							N/A
ProSet Intrafix® SafeSet	4182001A							N/A
ProSet Intrafix® SafeSet	4182002A							N/A
ProSet Intrafix® SafeSet	4182097							N/A
ProSet Intrafix® SafeSet	4182098							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Intrafix® SafeSet	4188137							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	40392390000014832Q	G2S 012974 0457 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4062877		G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4062878							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® Primeline	4110001							N/A
Intrafix® Primeline	4110002							N/A
ProSet Intrafix®	4186914							N/A
Intrafix® Primeline	4060563	40392390000014822N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063000A	40392390000007822W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063001CN							N/A
SafeSet	4063003CN							N/A
SafeSet	4063004CN							N/A
SafeSet	4063004SFCN							N/A
SafeSet	4063005CN							N/A
SafeSet	4063006CN							N/A
Infusomat® Plus Line	8700340CN	40392390000008622V	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700330CN							N/A
Infusomat® Plus Line SafeSet	8700240-20							N/A
Infusomat® Plus Line SafeSet	8700280							N/A
Infusomat® Plus Line SafeSet	8700300							N/A
Infusomat® Plus Line	8700340							N/A
Infusomat® Plus Line SafeSet	8700250							N/A
Infusomat® Plus Line SafeSet	8700240							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Plus Line SafeSet	8700220							N/A
Infusomat® Plus Line	8700330							N/A
Infusomat® Plus Line	8700320							N/A
ProSet Original Perfusor® Line	4092930	40392390000014802J	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Original Perfusor® Line	4183945							N/A
ProSet Original Perfusor® Line	4183943							N/A
ProSet Original Perfusor® Line	4183941							N/A
ProSet Original Perfusor® Line	4183938							N/A
Original Perfusor® Line	8723017CN							N/A
Original Perfusor® Line	8722919							N/A
Original Perfusor® Line	8723017							N/A
Original Perfusor® Line	8722919-20							N/A
Original Perfusor® Line	8723017-20							N/A
Original Perfusor® Line	8723018							N/A
ProSet Original Perfusor® Line	4183968							N/A
ProSet Original Perfusor® Line	4093000							N/A
ProSet Original Perfusor® Line	4183937							N/A
ProSet Original Perfusor® Line	4183942							N/A
ProSet Original Perfusor® Line	4183947							N/A
ProSet Original Perfusor® Line	4183930							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Original Perfusor® Line	4183933							N/A
ProSet Original Perfusor® Line	4183935							N/A
ProSet Original Perfusor® Line	4183936							N/A
Infusomat® Plus Line	8700350CN	403923900000086533	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-20		NB0123					N/A
Infusomat® Plus Line	8700360							N/A
Infusomat® Space Line	8700132SP	40392390000008693B	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					
Infusomat® Space Line	8270074SP	403923900000086635	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	8250908SP		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Plus Line	8700370CN	40392390000008632X	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700400		NB0123					N/A
Infusomat® Plus Line	8700370							N/A
Omnican® fine	9167641WE	4039239000001006ZF	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican® fine	9167650WE		NB0123					N/A
Omnican® fine	9167684WE							N/A
Omnican® fine	9167820WE							N/A
Omnican® fine	929G12S-03							N/A
Omnican® fine	929G12S-41							N/A
Omnican® fine	929G12S-43							N/A
Omnican® fine	931G04S-03							N/A
Omnican® fine	931G04S-41							N/A
Omnican® fine	931G04S-43							N/A
Omnican® fine	931G04SCN							N/A
Omnican® fine	931G04SCN1							N/A
Omnican® fine	931G06S-03							N/A
Omnican® fine	931G06S-41							N/A
Omnican® fine	931G06S-43							N/A
Omnican® fine	931G06S-AP							N/A
Omnican® fine	931G06SCN							N/A
Omnican® fine	931G06SCN1							N/A
Omnican® fine	931G08S-03							N/A
Omnican® fine	931G08S-41							N/A
Omnican® fine	931G08S-43							N/A
Omnican® fine	931G08S-44							N/A
Omnican® fine	932G04S-03							N/A
Omnican® fine	932G04S-41							N/A
Omnican® fine	932G04S-43							N/A
Omnican® fine	932G04S-AP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnican® fine	932G04SCN							N/A
Omnican® fine	932G04SCN1							N/A
Omnican® fine	932G05SCN							N/A
Omnican® fine	932G05SCN1							N/A
Omnican® fine	932G06S-03							N/A
Omnican® fine	932G06S-41							N/A
Omnican® fine	932G06S-43							N/A
Omnican® fine	932G06SCN							N/A
Omnican® fine	932G06SCN1							N/A
Omnican® fine	932P04							N/A
Omnican® fine	932P05							N/A
Omnican® fine	932P06							N/A
Infusomat® Plus Line SafeSet	8700270	40392390000020742A	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700260-20							N/A
Infusomat® Plus Line SafeSet	8700260							N/A
Original Perfusor® Line	8722865	40392390000008722Y	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700410	40392390000008642Z	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4182190SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4180639SP							N/A
ProSet Infusomat® Space Line	4180020SP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	8250918SP							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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	4188166SP							N/A
ProSet Infusomat® Space Line	4189980SP							N/A
ProSet Infusomat® Space Line	4186524SP							N/A
ProSet Infusomat® Space Line	4189979SP							N/A
ProSet Infusomat® Space Line	4089340SP							N/A
ProSet Infusomat® Space Line	8250905SP							N/A
ProSet Infusomat® Space Line	4183911							N/A
ProSet Infusomat® Space Line	4185489							N/A
ProSet Infusomat® Space Line	4187769SP							N/A
ProSet Infusomat® Space Line	8251284SP							N/A
ProSet Infusomat® Space Line	4185308SP							N/A
ProSet Infusomat® Space Line	8250904SP							N/A
ProSet Infusomat® Space Line	4186486SP							N/A
Infusomat® Space Line	8700095SP							N/A
Infusomat® Space Line	8700110SP							N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	4183901							N/A
ProSet Infusomat® Space Line	4189981SP							N/A
ProSet Infusomat® Space Line	4187377							N/A
ProSet Infusomat® Space Line	4182189SP							N/A
ProSet Infusomat® Space Line	8252659SP							N/A
ProSet Original Perfusor® Line	4185687	40392390000008712W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet 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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000014792Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	8252671 SP							N/A
Sangofix®	4050192	40392390000027342Z	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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	4039239000000039ZP	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4050151							N/A
Sangofix®	4051998							N/A
Sangofix®	4051998H							N/A
Sangofix®	4052005							N/A
Sangofix®	4052005H							N/A
Sangofix®	4052218H							N/A
Sangofix® Air	4080187							N/A
Sangofix®	4100514							N/A
Sangofix®	4117301							N/A
Sangofix®	4117549							N/A
Original Perfusor® Line	8723001	40392390000027242W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infuvalve®	4094000N	40392390000008102A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Combi-Stopper	4495209	40392390000008112C	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495101R		NB0123					N/A
Safeflow Extension Set	4097154N	40392390000008152L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Safeflow Extension Set	4097145N		NB0123					N/A
Safeflow Extension Set	4097154							N/A
Safeflow	409110H	40392390000008162N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Safeflow	409100CN		NB0123					N/A
Safeflow	409101H							N/A
Safeflow	409100H							N/A
Safeflow Extension Set	4097148N	403923900000027222S	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnican® 50	9151117S	40392390000009362Z	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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	403923900000093937	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
IBSA FSH/LH	9161530S							N/A
Serofine™ needle	16441MS	4039239000001007ZH	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Serofine™ needle	16443MS							N/A
Serofine® needle	16441EMD							N/A
B. Braun Pen Needle	16441CA							N/A
Pencylcap™	P1400060							N/A
Pencylcap™	P1400061							N/A
B. Braun Pen Needle	P1400062							N/A
Pencylcap™	U1244000							N/A
Pencylcap®	U1244100							N/A
B. Braun Pen Needle	P1400062CA							N/A
B. Braun Pen needle	U1244100CA							N/A
Pen Needle B. Braun F-Pen DS	P1400075							N/A
Serofine® needle	16443EMD							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drainobag® Lock 600 K 14	5523443	40392390000028193A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 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	4039239000001217ZW	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 100 Duo	9161376C							N/A
Omnifix® 100 Duo	9161376V							N/A
Omnifix® Luer Duo	4643011C	403923900000077633	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000077735	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Luer Lock Solo	4617022V-03							N/A
Omnifix® Luer Lock Solo	4617029V							N/A
Omnifix® Luer Lock Solo	4617053V							N/A
Omnifix® Luer Lock Solo	4617053V-03							N/A
Omnifix® Luer Lock Solo	4617100CA							N/A
Omnifix® Luer Lock Solo	4617100V							N/A
Omnifix® Luer Lock Solo	4617100V-03							N/A
Omnifix® Luer Lock Solo	4617207V							N/A
Omnifix® Luer Lock Solo	4617207V-03							N/A
Omnifix® Luer Lock Solo	4617304F							N/A
Omnifix® Luer Lock Solo	4617509F							N/A
Omnifix® Luer Lock Solo	4617509F-03							N/A
Omnifix® Luer Lock Solo	4617510F-06	4039239000000207022	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670002S-01	403923900000076936	G1 012974 0607	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Sterican® Safety Needle	4670005S-01		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000076834	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican®	4650034		NB0123					N/A
Sterican®	4657500		N/A					
Sterican®	4657519		N/A					
Sterican®	4657527		N/A					
Sterican®	4657543		N/A					
Sterican®	4657624		N/A					
Sterican®	4657640		N/A					
Sterican®	4657667		N/A					
Sterican®	4657675		N/A					
Sterican®	4657683		N/A					
Sterican®	4657705		N/A					
Sterican®	4657799		N/A					
Sterican®	4657853		N/A					
Sterican®	4660021		N/A					
Sterican®	4665112		N/A					
Sterican®	4665120		N/A					
Sterican®	4665317		N/A					
Sterican®	4665406		N/A					
Sterican®	4665457		N/A					
Sterican®	4665465		N/A					
Sterican®	4665503		N/A					
Sterican®	4665511		N/A					
Sterican®	4665600		N/A					
Sterican®	4665635		N/A					

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Sterican®	4665643							N/A
Sterican®	4665791							N/A
Sterican®	4667093							N/A
Sterican®	4667123							N/A
Sterican®	9180109							N/A
Sterican®	9180117							N/A
Sterican®	9186158							N/A
Sterican®	9186166							N/A
Sterican®	9186174							N/A
Sterican®	9186182							N/A
Injekt®-H Luer Duo	9166297	40392390000007742X	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022C	40392390000007752Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022UA							N/A
Injekt® Luer Duo	4645022V							N/A
Injekt® Luer Duo	4645057C							N/A
Injekt® Luer Duo	4645057UA							N/A
Injekt® Luer Duo	4645057V							N/A
Injekt® Luer Duo	4645065C							N/A
Injekt® Luer Duo	4645103C							N/A
Injekt® Luer Duo	4645103UA							N/A
Injekt® Luer Duo	4645103V							N/A
Injekt® Luer Duo	4645200C							N/A
Injekt® Luer Duo	4645200UA							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Injekt® Luer Duo	4645200V							N/A
Injekt® Luer Duo	4647220							N/A
Injekt®-F Luer Duo	9166033V							N/A
Sterican® Safety Needle	4670030SBR	403923900000076936	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670053SBR		NB0123					N/A
Contiplex® D	4898323	40392390000008522S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898325							N/A
Contiplex® D	4898305							N/A
Contiplex® D	4898308							N/A
Contiplex® D	4898311							N/A
Contiplex® D	4898335							N/A
Contiplex® D NRFit®	4898305NR							N/A
Contiplex® D NRFit®	4898335NR							N/A
Contiplex® D NRFit®	4898311NR							N/A
Contiplex® D NRFit®	4898323NR							N/A
Contiplex® D NRFit®	4898325NR							N/A
Contiplex® D	4895819NCN							N/A
Contiplex® D	4894235NCN							N/A
Contiplex® D	4894391NCN							N/A
Contiplex® D	4898205	40392390000008532U	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898211							N/A
Contiplex® D	4898235							N/A
Contiplex® C	4898115	403923900000085000	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® C	4898130		NB0123					N/A
Contiplex® C NRFit®	4898115NR							N/A
Contiplex® C NRFit®	4898130NR							N/A
Ultraplex® 360	4892603-01	40392390000008552Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Ultraplex® 360	4892603CN							N/A
Ultraplex® 360 NRFit®	4892603NR-01							N/A
Ultraplex® 360	4892605-01							N/A
Ultraplex® 360	4892605CN							N/A
Ultraplex® 360 NRFit®	4892605NR-01							N/A
Ultraplex® 360	4892608-01							N/A
Ultraplex® 360	4892608CN							N/A
Ultraplex® 360 NRFit®	4892608NR-01							N/A
Ultraplex® 360	4892610-01							N/A
Ultraplex® 360	4892610CN							N/A
Ultraplex® 360 NRFit®	4892610NR-01							N/A
Ultraplex® 360	4892615-01							N/A
Ultraplex® 360	4892615CN							N/A
Ultraplex® 360 NRFit®	4892615NR-01							N/A
Stimuplex® D	4892105	40392390000008502N	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® D	4892105-23							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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Stimuplex® D	4892208							N/A
Stimuplex® D	4892208-23							N/A
Stimuplex® D NRFit®	4892208NR							N/A
Stimuplex® Ultra 360®	4892503-01	40392390000008512Q	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Stimuplex® Ultra 360®	4892503-03		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000044ZG	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617014		NB0123					N/A
Omnifix® Lock	4617021							N/A
Omnifix® Lock	4617508F-01							N/A
Original Perfusor® Syringe 20 ml	8728615	403923900000077939	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728615C		NB0123					N/A
Original Perfusor® Syringe 20 ml	8728623	40392390000029923R	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728623C		NB0123					N/A
Original Perfusor® Syringe 50 ml	8728810F-04							N/A

Effective

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

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

Effective

Schedule of Devices

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

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)			Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Original Perfusor® Syringe 50 ml	8728810F-06							8728810F
Original Perfusor® Syringe 50 ml	8728810F-20							N/A
Original Perfusor® Syringe 50 ml	8728844F-04							N/A
Original Perfusor® Syringe 50 ml	8728844F-06	403923900000077939	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	8728844F
Original Perfusor® Syringe 50 ml	8728844F-20							N/A
Original Perfusor® Syringe 50 ml	8728852F-04							N/A
Original Perfusor® Syringe 50 ml	8728852F-06	40392390000029923R	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728852F-20							N/A
Original Perfusor® Syringe 50 ml	8728861F-04							N/A
Original Perfusor® Syringe 50 ml	8728861F-06	403923900000207124	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728861F-20							N/A
Original Perfusor® Syringe 50 ml	8728845F-01							N/A
Original Perfusor® Syringe 50 ml	8728845F-01	40392390000007802S	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450100	40392390000009993R	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450120							N/A
Cystofix®	4450130							N/A

Effective

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

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

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cystofix®	4450150							N/A
Cystofix®	4450160							N/A
Cystofix®	4450170							N/A
Cystofix®	4450180							N/A
Cystofix®	4450200	4039239000001000Z3	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450220		NB0123					N/A
Cystofix SG	4450410	4039239000001002Z7	G1 022239 0080	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix SG	4450412		NB0123 B.BRAUN MEDICAL SAS					N/A
Cystofix SG	4450414							N/A
Cystofix SG	4450416							N/A
Cystofix	4450010	4039239000001001Z5	G1 022239 0080	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450012		NB0123 B.BRAUN MEDICAL SAS		TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)		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	40392390000009272Y	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasco® OP Powdered	6031525		NB0123					N/A
Vasco® OP Powdered	6031532							N/A

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

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Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10

Effective

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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasco® OP Free	9208364							N/A
Drainobag® Connection Tube Bayonet	5524913	40392390000008052H	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	U2170701
Filter Needle	415040	4039239000000290000	G2S 012974 0457 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	4550404
Filter Hub	418021							4551001
Filter Straw	415020							4550200
Filter Straw	415021							4550250
Sterifix® Filter Straw 4"	339171							4550200N
Sterifix® Filter Straw 1.75"	339170							4550250N
Sterifix® Filter Needle 1.5"	339169							4550404N

Effective

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

Effective

Document History

Version	Description of Change
1.0	Initial version

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

Effective

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

UserName: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: Wednesday, 15 May 2024, 15:10 W. Europe Daylight Time
Meaning: Document signed as Author

=====

UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Wednesday, 15 May 2024, 15:24 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 15 May 2024, 16:49 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 15 May 2024, 17:22 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Arico, Mareike (sommrde)
Title: HC-QM - Head of QM active MD/ Head of Regulatory Affairs CoE AIS
Date: Wednesday, 15 May 2024, 21:34 W. Europe Daylight Time
Meaning: Approve Document

=====

Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10 Initiator: Anja Mai

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

UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
Date: Thursday, 16 May 2024, 07:36 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Thursday, 16 May 2024, 08:19 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Meyer, Frank (meyefrde)
Title: HC-QM-DE08 Vice President QM Applications Hospital Care
Date: Thursday, 16 May 2024, 09:09 W. Europe Daylight Time
Meaning: Final Release of the Document

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MANUFACTURER'S DECLARATION

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	B. Braun Melsungen AG
Manufacturer address and contact details	Carl-Braun Straße 1 34212 Melsungen GERMANY
Single Registration Number (SRN) (if available)	DE-MF-000000201

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Notified body name (if applicable)	TÜV SÜD Product Service GmbH	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	0123	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	(1) G1 012974 0607; (2) G1 019717 0032; (3) G1 022239 0080; (4) G2S 012974 0457	<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	(1) 2024-05-26; (2) 2024-05-26; (3) 2024-05-26; (4) 2024-05-26	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	2028-12-31	<input checked="" type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above or in the attached schedule
- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- ☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- ☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Quality Management System (QMS)

Choose one applicable statement:

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

➤ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

	Quality Management	Regulatory Affairs
Full Company Name	B. Braun Melsungen AG	B. Braun Melsungen AG
Location & Date	Melsungen, 2024-04-15	Melsungen, 2024-04-15
Signature	See electronic signature	See electronic signature
Print Name	(1) Thomas Brand; (2) Mareike Arico; (3) Dr. Frank Ritz	(4) Dr. Stefan Seidel; (5) Malte Loh; (6) Dr. Joachim Buenger
Title	(1) Vice President Quality Management for non-active Medical Devices; (2) Head of Quality Management Active Medical Devices/ Head of	(4) Head of Regulatory Affairs CoE Infusion & Pain Therapy; (5) Senior Manager Regulatory



	Regulatory Affairs CoE AIS; (3) Vice President QM Pharma; Hospital Care Division	Affairs; (6) Director Template & Submission Mgmt
Contact Details (at least email)	BBMAG-HC@bbraun.com	BBMAG-HC@bbraun.com
Version of document	Version 1.0	

B. Braun Melsungen AG - Document No.: G10 - Version: 1.0 - Document ID: RE-QM-DIV-000441 - Effective Date: 2024-05-16 -
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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Perfusor® compactplus	8717030	4039239000000038ZM	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus	8717050	40392390000005352B	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
OnlineSuite	876100	40392390000005552H	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Perfusor®	8719030	40392390000007562V	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Infusomat®	8719050	40392390000007552T	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus P	8717070	40392390000007492Y	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4116011F	4039239000000039ZP	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617006	4039239000000044ZG	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	932M04SE	403923900000018743B	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	931M08SE		NB0123					N/A
Drainobag® 600 V	5523606	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drug Library Manager Spaceplus	876203	403923900000169539	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drug Library Manager Spaceplus	876209	403923900000169539	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FR29914	403923900000249638	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FREU914							N/A
GLYCINE 1,5 % B. BRAUN	FREU934							N/A
GLYCINE 1,5 % B. BRAUN	FREU954							N/A
GLYCINE 1,5 % B. BRAUN	FREU974							N/A
NaCl 0,9 % B. BRAUN	FREU850	403923900000250128	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	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	40392390000026312N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	3637006							N/A
NaCl 0,9 % B. BRAUN	0069414E							N/A
NaCl 0,9 % B. BRAUN	3521360							N/A
NaCl 0,9 % B. BRAUN	3570120							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
NaCl 0,9 % B. BRAUN	3570130							N/A
NaCl 0,9 % B. BRAUN	3570140							N/A
NaCl 0,9 % B. BRAUN	0066570E							N/A
NaCl 0,9 % B. BRAUN	3521370							N/A
NaCl 0,9 % B. BRAUN	3570150							N/A
NaCl 0,9 % B. BRAUN	3570160							N/A
NaCl 0,9 % B. BRAUN	3570170							N/A
NaCl 0,9 % B. BRAUN	0066569E							N/A
NaCl 0,9 % B. BRAUN	3570110							N/A
Vitulia	450268	40392390000025022A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
NaCl 0,9 % B. BRAUN	3570370							N/A
NaCl 0,9 % B. BRAUN	3570380							N/A
NaCl 0,9 % B. BRAUN	3570390							N/A
NaCl 0,9 % B. BRAUN	391860							N/A
NaCl 0,9 % B. BRAUN	3570410							N/A
NaCl 0,9 % B. BRAUN	3570420							N/A
NaCl 0,9 % B. BRAUN	3570460	40392390000026302L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	3570470		NB0123					N/A
NaCl 0,9 % B. BRAUN	3570480							N/A
RINGER B. BRAUN	FREU864	40392390000025062J	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	FREU924		NB0123					FREU920
RINGER B. BRAUN	FREU944							N/A
RINGER B. BRAUN	FREU964							N/A
RINGER B. BRAUN	FREU984							N/A
RINGER B. BRAUN	3570000	40392390000026342U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	3570010		NB0123					N/A
RINGER B. BRAUN	3570020							N/A
RINGER B. BRAUN	3570030							N/A
RINGER B. BRAUN	3570040							N/A
RINGER B. BRAUN	3570050							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
RINGER B. BRAUN	3570060							N/A
RINGER B. BRAUN	3570611	40392390000026322Q	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570490
RINGER B. BRAUN	3570610							3570500
RINGER B. BRAUN	3570614							3570510
RINGER B. BRAUN	3570612							3570520
RINGER B. BRAUN	3570613	40392390000026332S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570530
Aqua B. Braun	FREU812	40392390000024973A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	FREU852							N/A
Aqua B. Braun	FREU912							N/A
Aqua B. Braun	FREU932							N/A
Aqua B. Braun	387872	40392390000026272X	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	387873		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Aqua B. Braun	387874							N/A
Aqua B. Braun	442464							N/A
Aqua B. Braun	442465							N/A
Aqua B. Braun	442466							N/A
Sterile Water for Irrigation	3637011							N/A
Aqua B. Braun	3521380	403923900000262933	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	3521390							N/A
Aqua B. Braun	3553949							N/A
Aqua B. Braun	3553957							N/A
Aqua B. Braun	0065729E							N/A
Aqua B. Braun	0066571E							N/A
Aqua B. Braun	0069415E							N/A
Aqua B. Braun	0082423E							N/A
Aqua B. Braun	0082479E							N/A
Sterile Water for Irrigation	3637007							N/A
Perifix® Catheter Connector	4513800	403923900000238732	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Catheter Connector	4513801							N/A
Perifix® Catheter Connector NRFit	4513800N-01							N/A
Perifix® Catheter Connector NRFit	4513801N-01							N/A
Infusomat® Space	8713050	40392390000007462S	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Space P	8713070	40392390000007472U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Perfusor® Space	8713030	40392390000007482W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Enteroport® plus	8710355	40392390000007452Q	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200	40392390000008622V	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200-20							N/A
Infusomat® Plus Line SafeSet	8700210							N/A
Infusomat® Plus Line	8700310							N/A
Infusomat® Plus Line	8700310-20							N/A
Infusomat® Plus Line	8700310CN							N/A
Cyto-Set® Infusomat® Space	8250414SP	40392390000007832Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set® Infusomat® Space	835414SP							N/A
Cyto-Set® Infusomat® Space	835817SP							N/A
Cyto-Set® Infusomat® Space	835820SP							N/A
Cyto-Set® Infusomat® Space	835917SP							N/A
Cyto-Set® Infusomat® Space	835920SP							N/A
Cyto-Set® Infusomat® plus	8700420							N/A
Cyto-Set® Infusomat® plus	8700430							N/A
Cyto-Set® Infusomat® plus	8700440							N/A
Cyto-Set® Infusomat® plus	8700450							N/A
Cyto-Set® Infusomat® plus	8700460							N/A
Cyto-Set® Infusomat® plus	8700470							N/A
Cyto-Set® Infusomat® plus	8700480							N/A
Cyto-Set® Infusomat® plus	8700490							N/A
Cyto-Set® Line	A2581NF	403923900000078432	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Line	A2582NF		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set® Mix	A2900N							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	4039239000008602R	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® A	4894539							N/A
Stimuplex® A	4894367							N/A
Stimuplex® A	4894502							N/A
Stimuplex® A	4894375							N/A
Stimuplex® A	4894260							N/A
Stimuplex® A	4894278							N/A
Stimuplex® A	4894278NR							N/A
Stimuplex® A	4894375NR							N/A
Stimuplex® A	4894260NR							N/A
Stimuplex® A	4894367NR							N/A
Stimuplex® A	4894539NR							N/A
Stimuplex® A	4894502NR							N/A
Stimuplex® A	4894251 NR							N/A
Easypump® II LT 60-12	4540002	40392390000023452J	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Easypump® II LT 60-12	4540002-07							N/A
Easypump® II LT 60-12	4540002-20							N/A
Easypump® II LT 500-12.5	4540003							N/A
Easypump® II LT 500-12.5	4540003-07							N/A
Easypump® II LT 500-12.5	4540003-20							N/A
Easypump® II LT 80-16	4540004							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II LT 80-16	4540004-07							N/A
Easypump® II LT 80-16	4540004-20							N/A
Easypump® II LT 125-25	4540006							N/A
Easypump® II LT 125-25	4540006-07							N/A
Easypump® II LT 125-25	4540006-20							N/A
Easypump® II LT 270-27	4540008							N/A
Easypump® II LT 270-27	4540008-07							N/A
Easypump® II LT 270-27	4540008-20							N/A
Easypump® II LT 60-30	4540010							N/A
Easypump® II LT 60-30	4540010-07							N/A
Easypump® II LT 60-30	4540010-20							N/A
Easypump® II LT 120-30	4540012							N/A
Easypump® II LT 120-30	4540012-07							N/A
Easypump® II LT 120-30	4540012-20							N/A
Easypump® II LT 400-40	4540014							N/A
Easypump® II LT 400-40	4540014-07							N/A
Easypump® II LT 400-40	4540014-20							N/A
Easypump® II LT 100-50	4540016							N/A
Easypump® II LT 100-50	4540016-07							N/A
Easypump® II LT 100-50	4540016-20							N/A
Easypump® II LT 270-54	4540018							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II LT 270-54	4540018-07							N/A
Easypump® II LT 270-54	4540018-20							N/A
Easypump® II LT 400-80	4540022							N/A
Easypump® II LT 400-80	4540022-07							N/A
Easypump® II LT 400-80	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II ST 50-1	4540044-07							N/A
Easypump® II ST 50-1	4540044-20							N/A
Easypump® II ST 100-1	4540046							N/A
Easypump® II ST 100-1	4540046-07							N/A
Easypump® II ST 100-1	4540046-20							N/A
Easypump® II ST 250-1	4540048							N/A
Easypump® II ST 250-1	4540048-07							N/A
Easypump® II ST 250-1	4540048-20							N/A
Easypump® II ST 250-1,5	4540050							N/A
Easypump® II ST 250-1,5	4540050-07							N/A
Easypump® II ST 250-1,5	4540050-20							N/A
Easypump® II ST 400-2	4540052							N/A
Easypump® II ST 400-2	4540052-07							N/A
Easypump® II ST 400-2	4540052-20							N/A
Easypump® II ST 500-2	4540054							N/A
Easypump® II ST 500-2	4540054-07							N/A
Easypump® II ST 500-2	4540054-20							N/A
Easypump® II ST 100-2	4540056							N/A
Easypump® II ST 100-2	4540056-07							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000085836	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	4505000
Spinal Introducer	4500059-13		NB0123					4500059
Contiplex® S 360	4898650CN	40392390000008542W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® S 360	4898610CN		NB0123					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	403923900000238834	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Filter NRFit	4515501N-01		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® S Ultra 360® NRFit®	4898650NR-27	40392390000008542W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® S Ultra 360® NRFit®	4898610NR-27							N/A
Contiplex® S Ultra 360® NRFit®	4898615NR-27							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898704NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898705NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898710NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898715NR-01							N/A
Contiplex® Tuohy Ultra 360®	4898704-01							N/A
Contiplex® Tuohy Ultra 360®	4898705-01							N/A
Contiplex® Tuohy Ultra 360®	4898710-01							N/A
Contiplex® Tuohy Ultra 360®	4898715-01							N/A
Contiplex® Tuohy Ultra 360®	4898704-27							N/A
Contiplex® Tuohy Ultra 360®	4898705-27							N/A
Contiplex® Tuohy Ultra 360®	4898710-27							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® Tuohy Ultra 360®	4898715-27							N/A
Discofix®	4099117	40392390000007582Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix®	4095111		NB0123					N/A
Discofix®	4095120							N/A
Discofix®	4095146							N/A
Discofix®	4095111IN							N/A
Discofix®	409511CN							N/A
Discofix®	409512CN							N/A
Discofix®	16466							N/A
Discofix®	4098102							N/A
Discofix®	409810CN							N/A
Discofix®	4098218							N/A
Discofix®	409821CN							N/A
Discofix®	4098501							N/A
Discofix®	4098234							N/A
Discofix®	4098080							N/A
Discofix®	4055150							N/A
Discofix®	4055145							N/A
Discofix®	4055146							N/A
Discofix®	4055149							N/A
Discofix®	4055147							N/A
Discofix®	4055148							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix®	4099010							N/A
Discofix®	4095210							15809
Nutritub® ENFit® intestinal	9246605	40392390000029463J	G1 019717 0032 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246584
Nutritub® ENFit® intestinal	9246604		B. Braun Avitum Italy S.p.A.					9246586
Nutritub® ENFit® intestinal	9246604							9246576
Nutritub® ENFit® intestinal	9246604							9246578
Nutritub® Gastral Basic ENFit®	9246603	40392390000008172Q	G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246519
Nutritub® Gastral Basic ENFit®	9246602		NB0123					9246518
Nutritub® Gastral Basic ENFit®	9246601		B. Braun Avitum Italy S.p.A.					9246516
Nutritub® Gastral Basic ENFit®	9246600							9246550
Nutritub® Gastral Basic ENFit®	9246599							9246515
Nutritub® Gastral Basic ENFit®	9246598							9246592
Nutritub® Gastral Basic ENFit®	9246597							9246514
Nutritub® Gastral Basic ENFit®	9246597							9246513
Nutritub® Gastral Basic ENFit®	9246597							9246541
Nutritub® Gastral Basic ENFit®	9246597							9246543

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Nutritub® Gastral Basic ENFit®	9246596							9246512
Nutritub® Gastral Basic ENFit®	9246595							9246517 9246525 9246533 9246535
Nutritub® Gastral Basic ENFit®	9246594							9246509 9246511
Nutritub® Gastral Basic ENFit®	9246593							9246508
Infusomat® Space Line	8250832SP							8250833SP
Infusomat® Space Line	8250834SP		NB0123		TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	8250835SP
IN-Stopper	4238010	40392390000028583L	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
IN-Stopper	4238011		NB0123					N/A
Combi-Stopper	4495101	40392390000008112C	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495152		NB0123					N/A
Combifix Adapter	5206634	40392390000008122E	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Combifix Adapter	5206642		NB0123					N/A
Original Perfusor® Line	87229910	40392390000008702U	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
			NB0123					
Pleurofix® No. 1	4461002	40392390000007902V	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleurofix® No. 2	4461037		NB0123					N/A
Seldinger Introducer Needle	4206096	40392390000007442N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Seldinger Introducer Needle	4206100		NB0123					N/A
Injekt® 40 Duo	9166432C	4039239000000121823	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® 40 Duo	9166432V		NB0123					N/A
Introcan Safety® 3	4251127-01	40392390000007652W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety® 3	4251127-03		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Introcan Safety® 3	4251134-01							N/A
Introcan Safety® 3	4251134-03							N/A
Introcan Safety® 3	4251134-04							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Infusomat® Space Line	8700036SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line	8700435SP							N/A
Infusomat® Space Line SafeSet	8701148SP							N/A
Infusomat® Space Line	8270066SP-01	403923900000086635	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8270066SP
Infusomat® Space Line	8270066SP-26							N/A
Infusomat® Plus Line	8700350-01	403923900000086533	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-26							N/A
Enteroport® ENFit® Set		4039239000000263732	G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8721748

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set®	8250266	40392390000007832Y	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set®	8250366							N/A
ProSet Cyto-Set®	8250370							N/A
ProSet Cyto-Set® 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

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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set® Mix	4188925							N/A
ProSet Cyto-Set® Mix	4188926							N/A
ProSet Cyto-Set® Pump Adapter	4182704	403923900000078534	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Pump Adapter	A1673SO		NB0123					N/A
Dosifix®	4037011	40392390000008192U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Dosifix®	4037012		NB0123					N/A
Dosifix®	4037013							N/A
Dosifix®	4037032							N/A
Dosifix®	4037031	40392390000008202D	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					
Heidelberger Extension Tubing	4033809	403923900000078636	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4034589		NB0123					N/A
Heidelberger Extension Tubing	4038703							N/A
Heidelberger Extension Tubing	4055128							N/A
Heidelberger Extension Tubing	4055136							N/A
Extension Line, Type: Heidelberg	4097130							N/A
Extension Line, Type: Heidelberg	4097173							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Extension Line, Type: Heidelberg	4097190							N/A
Extension Line, Type: Heidelberg	4097262							N/A
Extension Line, Type: Heidelberg	4097290							N/A
Extension Line, Type: Heidelberg	4097291							N/A
Extension Line, Type: Heidelberg	4097300							N/A
Extension Line, Type: Heidelberg	4097408							N/A
Introcan® Certo	4055764	40392390000007612N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan® Certo	4251300							N/A
Introcan® Certo	4251318							N/A
Introcan® Certo	4251326							N/A
Introcan® Certo	4251334							N/A
Introcan® Certo	4251342							N/A
Introcan® Certo	4251350							N/A
Introcan® Certo	4251369							N/A
Introcan®	4252071B							N/A
Introcan®	4252098B							N/A
Introcan®	4252110B							N/A
Introcan®	4252136B							N/A
Introcan®	4252160B							N/A
Introcan®	4252217B							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan®	4252322B							N/A
Introcan®-W Certo	4253302							N/A
Introcan®-W Certo	4253310							N/A
Introcan®-W Certo	4253329							N/A
Introcan®-W Certo	4253337							N/A
Introcan®-W Certo	4253345							N/A
Introcan®-W Certo	4253353							N/A
Introcan®-W Certo	4253361							N/A
Introcan®-W	4254074B							N/A
Introcan®-W	4254090B							N/A
Introcan®-W	4254112B							N/A
Introcan®-W	4254139B							N/A
Introcan®-W	4254171B							N/A
Introcan®-W	4254210B							N/A
Introcan®-W	4254325B							N/A
Discofix® C Safeflow	16494CCN	40392390000007602L	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C Safeflow	16495CCN		NB0123					N/A
Discofix® C Safeflow	16501CCN							N/A
Discofix® C Safeflow	16500CCN							N/A
Discofix® C Safeflow	16540CCN							N/A
Discofix® C Safeflow	16520CCN							N/A
Intrapur®-Neonat	4099451	40392390000008082P	G1 012974 0607	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrapur®	4093216		NB0123					N/A
Sterifix®	4184637							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000075933	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16540C							N/A
Discofix® C	16494C							N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix® C	16720C							N/A
Discofix® C	16520CSF							N/A
Discofix® C	16520C							N/A
Discofix® C	16701C							N/A
Discofix® C	16496C							N/A
Discofix® C	16501CSF-1							N/A
Discofix® C	RU16496C							N/A
Discofix® C	RU16495C							N/A
Discofix® C	CN16496C							N/A
Discofix® C	RU16494C							N/A
Discofix® C	EC16494C							N/A
Discofix® C	CN16494C							N/A
Discofix® C	16611C							N/A
Discofix® C	16608C							N/A
Discofix® C	16600C							N/A
Discofix® C	16501CSF							N/A
Pleuracan®	4462556	40392390000007922Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleuracan® B	4462505		NB0123					N/A
Pleuracan® Back-Check Valve	4462564	403923900000079333	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600	5523682	4039239000000281736	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16700C	403923900000075933	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16500C		NB0123					N/A
Discofix® C	16495C							N/A
Discofix® C	16560CSF							N/A
Discofix® C	16901C							N/A
Discofix® C	16615C							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000026953G	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4052197							N/A
Heidelberger Extension Tubing	4052197H							N/A
Introcan Safety®	4251601-01	40392390000007632S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety®	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan Safety®	4252519-03							N/A
Introcan Safety®	4252519-04							N/A
Introcan Safety®	4252520-01							N/A
Introcan Safety®	4252527-01							N/A
Introcan Safety®	4252527-03							N/A
Introcan Safety®	4252535-01							N/A
Introcan Safety®	4252535-03							N/A
Introcan Safety®	4252535-04							N/A
Introcan Safety®	4252543-01							N/A
Introcan Safety®	4252551-01							N/A
Introcan Safety®	4252551-03							N/A
Introcan Safety®	4252551-04							N/A
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

Effective

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

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Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan Safety® W	4253604-01							N/A
Introcan Safety® W	4253604-03							N/A
Introcan Safety® W	4253604-04							N/A
Introcan Safety® W	4253604JP							N/A
Introcan Safety® W	4253612-01							N/A
Introcan Safety® W	4253612-03							N/A
Introcan Safety® W	4253612-04							N/A
Introcan Safety® W	4253639-01							N/A
Introcan Safety® W	4253639-03							N/A
Introcan Safety® W	4253639JP							N/A
Introcan Safety® W	4253639-04							N/A
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

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000008082P	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Intrapur®	4183925							N/A
ProSet Intrapur®	4183926							N/A
ProSet Intrapur®	4183927							N/A
ProSet Intrapur®	4183948							N/A
ProSet Intrapur®	4183949							N/A
ProSet Intrapur®	4184004							N/A
ProSet Intrapur®	4184006							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Intrapur®	4184007							N/A
ProSet Intrapur®	4184008							N/A
ProSet Intrapur®	4098725							N/A
ProSet Intrapur®	4081002							N/A
ProSet Sterifix® Neonat	4099265							N/A
ProSet Intrapur®	4187822							N/A
ProSet Intrapur®	4184001							N/A
ProSet Intrapur®	4183255							N/A
ProSet Intrapur®	4183245							N/A
ProSet Intrapur®	4183240							N/A
ProSet Intrapur®	4180351							N/A
ProSet Intrapur®	4180350							N/A
ProSet Discofix® C	4188960	403923900000075933	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Discofix® C	4188959							N/A
ProSet Discofix® C	4188957							N/A
ProSet Discofix® C	4188105							N/A
ProSet Discofix® C	4188071							N/A
ProSet Discofix® C	4187954							N/A
ProSet Discofix® C	4187826							N/A
ProSet Discofix® C	4187202							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4187199							N/A
ProSet Discofix® C	4187032							N/A
ProSet Discofix® C	4184963							N/A
ProSet Discofix® C	4184491							N/A
ProSet Discofix® C	4184246							N/A
ProSet Discofix® C	4184030							N/A
ProSet Discofix® C	4184022							N/A
ProSet Discofix® C	4182635							N/A
ProSet Discofix® C	4181234							N/A
ProSet Discofix® C	4180965							N/A
ProSet Discofix® C	4086481							N/A
ProSet Discofix® C	4085230							N/A
ProSet Discofix® C	4085213							N/A
ProSet Discofix® C	4187203							N/A
ProSet Discofix® C	4182308							N/A
ProSet Discofix® C	4187527							N/A
ProSet Discofix® C	4180437							N/A
ProSet Discofix® C	4183088							N/A
ProSet Discofix® C	4088698							N/A
ProSet Discofix® C	4084792							N/A
ProSet Discofix® C	4085300SF							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4085086							N/A
ProSet Discofix® C	4181027							N/A
ProSet Discofix® C	4184005							N/A
ProSet Discofix® C	4187291							N/A
ProSet Discofix® C	4183312							N/A
ProSet Discofix® C	4185366							N/A
ProSet Discofix® C	4185927							N/A
ProSet Discofix® C	4188188							N/A
ProSet Discofix® C	4086482							N/A
ProSet Discofix® C	4184327							N/A
ProSet Discofix® C	4180439							N/A
ProSet Discofix® C	4180306							N/A
ProSet Discofix® C	4182944							N/A
ProSet Discofix® C	4083255							N/A
ProSet Discofix® C	4187911							N/A
ProSet Discofix® C	4187823							N/A
ProSet Discofix® C	4187878							N/A
ProSet Discofix® C	4085168							N/A
ProSet Discofix® C	4189821							N/A
ProSet Discofix® C	4188958							N/A
ProSet Discofix® C	4187213							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4187880							N/A
ProSet Discofix® C	4083254							N/A
ProSet Discofix® C	4189847							N/A
ProSet Discofix® C	4188198							N/A
ProSet Discofix® C	4183510							N/A
ProSet Discofix® C	4187033							N/A
ProSet Discofix® C	4188072							N/A
ProSet Discofix® C	4183787							N/A
ProSet Discofix® C	4180678							N/A
ProSet Discofix® C	4180679							N/A
ProSet Discofix® C	4187879							N/A
ProSet Discofix® C	4185928							N/A
ProSet Discofix® C	4086879							N/A
ProSet Discofix® C	4188047							N/A
ProSet Discofix® C	4189839							N/A
ProSet Discofix® C	4183852							N/A
ProSet Discofix® C	4185985							N/A
ProSet Discofix® C	4085450SF							N/A
ProSet Discofix® C	4089464							N/A
ProSet Discofix® C	4182737							N/A
ProSet Discofix® C	4180300							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4183777							N/A
ProSet Discofix® C	4185972							N/A
ProSet Discofix® C	4184521							N/A
ProSet Discofix® C	4182652							N/A
ProSet Discofix® C	4184483							N/A
ProSet Discofix® C	4087930							N/A
ProSet Discofix® C	4184817							N/A
ProSet Discofix® C	4187391							N/A
ProSet Discofix® C	4182720							N/A
ProSet Discofix® C	4185821N							N/A
ProSet Discofix® C	4085434SF							N/A
ProSet Discofix® C	4188225							N/A
ProSet Discofix® C	4186580							N/A
ProSet Discofix® C	4186579							N/A
ProSet Discofix® C	4085500SF							N/A
ProSet Discofix® C	4181778							N/A
ProSet Discofix® C	4180459							N/A
ProSet Discofix® C	4188510							N/A
ProSet Discofix® C	4180438							N/A
ProSet Discofix® C	4086945							N/A
ProSet Discofix® C	4187898							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4185021	40392390000007622Q	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Discofix® C	4187529							N/A
ProSet Discofix® C	4088520							N/A
ProSet Discofix® C	4181028							N/A
ProSet Discofix® C	4182638							N/A
ProSet Discofix® C	4088699							N/A
ProSet Discofix® C	4180120							N/A
ProSet Discofix® C	4180677							N/A
ProSet Discofix® C	4182633							N/A
ProSet Discofix® C	4182639							N/A
ProSet Discofix® C	4187838							N/A
ProSet Discofix® C	4084510							N/A
ProSet Discofix® C	4182651							N/A
ProSet Discofix® C	4187834							N/A
ProSet Discofix® C	4180445							N/A
ProSet Discofix® C	4083777							N/A
ProSet Discofix® C	4187308							N/A
ProSet Discofix® C	4184424							N/A
ProSet Discofix® C	4182182							N/A
Vasofix® Braunüle®	4268091B	40392390000007622Q	NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasofix® Braunüle®	4268113B							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasofix® Braunüle®	4268130B							N/A
Vasofix® Braunüle®	4268156B							N/A
Vasofix® Braunüle®	4268172B							N/A
Vasofix® Braunüle®	4268210B							N/A
Vasofix® Braunüle®	4268334B							N/A
Vasofix® Certo	4269071							N/A
Vasofix® Certo	4269098							N/A
Vasofix® Certo	4269110							N/A
Vasofix® Certo	4269136							N/A
Vasofix® Certo	4269152							N/A
Vasofix® Certo	4269179							N/A
Vasofix® Certo	4269217							N/A
Vasofix® Certo	4269225							N/A
Vasofix® Certo	4269330							N/A
Extension Line	4051807							40392390000007893C
Extension Line	4054393	NB0123	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						

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000007642U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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
Vasofix® Safety	4268210S-03							N/A
Vasofix® Safety	4268334S-01							N/A

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

Effective

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasofix® Safety	4269179S-03							N/A
Vasofix® Safety	4269179SIN							N/A
Vasofix® Safety	4269179S-20							N/A
Vasofix® Safety	4269217S-01							N/A
Vasofix® Safety	4269217S-03							N/A
Vasofix® Safety	4269217S-20							N/A
Vasofix® Safety	4269225S-01							N/A
Vasofix® Safety	4269225S-03							N/A
Vasofix® Safety	4269225S-20							N/A
Vasofix® Safety	4269330S-01							N/A
Vasofix® Safety	4269330S-03							N/A
Vasofix® Safety	4269330S-20							N/A
ProSet Spiral Line	4091728	40392390000007893C	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Spiral Line	4091736							N/A
ProSet Spiral Line	4091740							N/A
ProSet Spiral Line	4091752							N/A
ProSet Spiral Line	4092539							N/A
ProSet Spiral Line	4092937							N/A
ProSet Spiral Line	4092945							N/A
ProSet Spiral Line	4092953							N/A
ProSet Spiral Line	4092961							N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Extension Line	4095251							N/A
ProSet Extension Line	4097531							N/A
Extension Line	4097572							N/A
ProSet Spiral Line	4099362							N/A
ProSet Extension Line	4185841							N/A
ProSet Extension Line	4185842							N/A
ProSet Spiral Line	4187466							N/A
ProSet Spiral Line	4187467							N/A
ProSet Spiral Line	4187468							N/A
ProSet Spiral Line	4187469							N/A
ProSet Spiral Line	4188080							N/A
Extension Line	9500049							N/A
Extension Line	9500057							N/A
Extension Line	9500065							N/A
Infusomat@plus Line SafeSet	8700390	40392390000014782X	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat@plus Line SafeSet	8700391		NB0123					N/A
Infusomat@plus Line SafeSet	8700392	403923900000259235	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Space Line SafeSet	8700140SP	40392390000014772V	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line SafeSet	8700141SP		NB0123					N/A
Infusomat® Space Line SafeSet	8700142SP	403923900000259133	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4060369L	40392390000007812U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4060407		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® SafeSet	4063005							N/A
Intrafix® SafeSet	4063006							N/A
Drainobag® Basse Pression	5524237	403923900000281736	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 300	5522390							N/A
Drainobag® 150	5523753							N/A
Drainobag® Lock 150	5523761							N/A
Drainobag® Lock 150	55237611							N/A
Drainobag® Lock 400	5523602							U2000600
Drainobag® 600 V	5523605							N/A
Drainobag® Lock 600 V	5523648	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 V	5523649							N/A
Drainobag® Basse Pression TL	5524210							N/A
Drainobag® 300 V	5522322							N/A
Drainobag® Lock 300 V	5522340							N/A
Drainobag® Lock 300 V	55223401							N/A
Drainobag® 150 V	5523702							N/A
Drainobag® 150 VL	5523710							N/A
Drainobag® Lock 150 V	5523729							N/A
Drainobag® Lock 150 VL	5523737							N/A
Drainobag® Lock 150 VL	55237371							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drainobag® 400 V	5523601							U2000500
Drainobag® Lock 400 V	5523603							U2000700
Drainobag® Lock 600 K 10	5523400	40392390000028193A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 K 10	5523401							N/A
Drainobag® Lock 600 K 12	5523427							N/A
Drainobag® Lock 600 K 12	5523428							N/A
Intrafix® SafeSet	4063144	40392390000007812U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4063148							N/A
Intrafix® Primeline	4063287							N/A
ProSet Intrafix® Primeline	4088549							N/A
Intrafix® SafeSet	4110000							N/A
Intrafix® SafeSet	4110010							N/A
ProSet Intrafix® Primeline	4180038							N/A
ProSet Intrafix® SafeSet	4182001A							N/A
ProSet Intrafix® SafeSet	4182002A							N/A
ProSet Intrafix® SafeSet	4182097							N/A
ProSet Intrafix® SafeSet	4182098							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Intrafix® SafeSet	4188137							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	40392390000014832Q	G2S 012974 0457 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4062877		G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4062878							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® Primeline	4110001							N/A
Intrafix® Primeline	4110002							N/A
ProSet Intrafix®	4186914							N/A
Intrafix® Primeline	4060563	40392390000014822N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063000A	40392390000007822W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063001CN							N/A
SafeSet	4063003CN							N/A
SafeSet	4063004CN							N/A
SafeSet	4063004SFCN							N/A
SafeSet	4063005CN							N/A
SafeSet	4063006CN							N/A
Infusomat® Plus Line	8700340CN	40392390000008622V	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700330CN							N/A
Infusomat® Plus Line SafeSet	8700240-20							N/A
Infusomat® Plus Line SafeSet	8700280							N/A
Infusomat® Plus Line SafeSet	8700300							N/A
Infusomat® Plus Line	8700340							N/A
Infusomat® Plus Line SafeSet	8700250							N/A
Infusomat® Plus Line SafeSet	8700240							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Plus Line SafeSet	8700220							N/A
Infusomat® Plus Line	8700330							N/A
Infusomat® Plus Line	8700320							N/A
ProSet Original Perfusor® Line	4092930	40392390000014802J	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Original Perfusor® Line	4183945							N/A
ProSet Original Perfusor® Line	4183943							N/A
ProSet Original Perfusor® Line	4183941							N/A
ProSet Original Perfusor® Line	4183938							N/A
Original Perfusor® Line	8723017CN							N/A
Original Perfusor® Line	8722919							N/A
Original Perfusor® Line	8723017							N/A
Original Perfusor® Line	8722919-20							N/A
Original Perfusor® Line	8723017-20							N/A
Original Perfusor® Line	8723018							N/A
ProSet Original Perfusor® Line	4183968							N/A
ProSet Original Perfusor® Line	4093000							N/A
ProSet Original Perfusor® Line	4183937							N/A
ProSet Original Perfusor® Line	4183942							N/A
ProSet Original Perfusor® Line	4183947							N/A
ProSet Original Perfusor® Line	4183930							N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Original Perfusor® Line	4183933							N/A
ProSet Original Perfusor® Line	4183935							N/A
ProSet Original Perfusor® Line	4183936							N/A
Infusomat® Plus Line	8700350CN	403923900000086533	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-20		NB0123					N/A
Infusomat® Plus Line	8700360							N/A
Infusomat® Space Line	8700132SP	40392390000008693B	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					
Infusomat® Space Line	8270074SP	403923900000086635	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	8250908SP		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Plus Line	8700370CN	40392390000008632X	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700400		NB0123					N/A
Infusomat® Plus Line	8700370							N/A
Omnican® fine	9167641WE	4039239000001006ZF	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican® fine	9167650WE		NB0123					N/A
Omnican® fine	9167684WE							N/A
Omnican® fine	9167820WE							N/A
Omnican® fine	929G12S-03							N/A
Omnican® fine	929G12S-41							N/A
Omnican® fine	929G12S-43							N/A
Omnican® fine	931G04S-03							N/A
Omnican® fine	931G04S-41							N/A
Omnican® fine	931G04S-43							N/A
Omnican® fine	931G04SCN							N/A
Omnican® fine	931G04SCN1							N/A
Omnican® fine	931G06S-03							N/A
Omnican® fine	931G06S-41							N/A
Omnican® fine	931G06S-43							N/A
Omnican® fine	931G06S-AP							N/A
Omnican® fine	931G06SCN							N/A
Omnican® fine	931G06SCN1							N/A
Omnican® fine	931G08S-03							N/A
Omnican® fine	931G08S-41							N/A
Omnican® fine	931G08S-43							N/A
Omnican® fine	931G08S-44							N/A
Omnican® fine	932G04S-03							N/A
Omnican® fine	932G04S-41							N/A
Omnican® fine	932G04S-43							N/A
Omnican® fine	932G04S-AP							N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnican® fine	932G04SCN							N/A
Omnican® fine	932G04SCN1							N/A
Omnican® fine	932G05SCN							N/A
Omnican® fine	932G05SCN1							N/A
Omnican® fine	932G06S-03							N/A
Omnican® fine	932G06S-41							N/A
Omnican® fine	932G06S-43							N/A
Omnican® fine	932G06SCN							N/A
Omnican® fine	932G06SCN1							N/A
Omnican® fine	932P04							N/A
Omnican® fine	932P05							N/A
Omnican® fine	932P06							N/A
Infusomat® Plus Line SafeSet	8700270	40392390000020742A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700260-20							N/A
Infusomat® Plus Line SafeSet	8700260							N/A
Original Perfusor® Line	8722865	40392390000008722Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700410	40392390000008642Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4182190SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4180639SP							N/A
ProSet Infusomat® Space Line	4180020SP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	8250918SP							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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	4188166SP							N/A
ProSet Infusomat® Space Line	4189980SP							N/A
ProSet Infusomat® Space Line	4186524SP							N/A
ProSet Infusomat® Space Line	4189979SP							N/A
ProSet Infusomat® Space Line	4089340SP							N/A
ProSet Infusomat® Space Line	8250905SP							N/A
ProSet Infusomat® Space Line	4183911							N/A
ProSet Infusomat® Space Line	4185489							N/A
ProSet Infusomat® Space Line	4187769SP							N/A
ProSet Infusomat® Space Line	8251284SP							N/A
ProSet Infusomat® Space Line	4185308SP							N/A
ProSet Infusomat® Space Line	8250904SP							N/A
ProSet Infusomat® Space Line	4186486SP							N/A
Infusomat® Space Line	8700095SP							N/A
Infusomat® Space Line	8700110SP							N/A

Effective

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	4183901							N/A
ProSet Infusomat® Space Line	4189981SP							N/A
ProSet Infusomat® Space Line	4187377							N/A
ProSet Infusomat® Space Line	4182189SP							N/A
ProSet Infusomat® Space Line	8252659SP							N/A
ProSet Original Perfusor® Line	4185687	40392390000008712W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet 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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000014792Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	8252671 SP							N/A
Sangofix®	4050192	40392390000027342Z	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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	4039239000000039ZP	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4050151							N/A
Sangofix®	4051998							N/A
Sangofix®	4051998H							N/A
Sangofix®	4052005							N/A
Sangofix®	4052005H							N/A
Sangofix®	4052218H							N/A
Sangofix® Air	4080187							N/A
Sangofix®	4100514							N/A
Sangofix®	4117301							N/A
Sangofix®	4117549							N/A
Original Perfusor® Line	8723001	40392390000027242W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infuvalve®	4094000N	40392390000008102A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Combi-Stopper	4495209	40392390000008112C	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495101R		NB0123					N/A
Safeflow Extension Set	4097154N	40392390000008152L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Safeflow Extension Set	4097145N		NB0123					N/A
Safeflow Extension Set	4097154							N/A
Safeflow	409110H	40392390000008162N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Safeflow	409100CN		NB0123					N/A
Safeflow	409101H							N/A
Safeflow	409100H							N/A
Safeflow Extension Set	4097148N	403923900000027222S	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnican® 50	9151117S	40392390000009362Z	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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	403923900000093937	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
IBSA FSH/LH	9161530S							N/A
Serofine™ needle	16441MS	4039239000001007ZH	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Serofine™ needle	16443MS							N/A
Serofine® needle	16441EMD							N/A
B. Braun Pen Needle	16441CA							N/A
Pencylcap™	P1400060							N/A
Pencylcap™	P1400061							N/A
B. Braun Pen Needle	P1400062							N/A
Pencylcap™	U1244000							N/A
Pencylcap®	U1244100							N/A
B. Braun Pen Needle	P1400062CA							N/A
B. Braun Pen needle	U1244100CA							N/A
Pen Needle B. Braun F-Pen DS	P1400075							N/A
Serofine® needle	16443EMD							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drainobag® Lock 600 K 14	5523443	40392390000028193A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 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	4039239000001217ZW	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 100 Duo	9161376C							N/A
Omnifix® 100 Duo	9161376V							N/A
Omnifix® Luer Duo	4643011C	403923900000077633	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000077735	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Luer Lock Solo	4617022V-03							N/A
Omnifix® Luer Lock Solo	4617029V							N/A
Omnifix® Luer Lock Solo	4617053V							N/A
Omnifix® Luer Lock Solo	4617053V-03							N/A
Omnifix® Luer Lock Solo	4617100CA							N/A
Omnifix® Luer Lock Solo	4617100V							N/A
Omnifix® Luer Lock Solo	4617100V-03							N/A
Omnifix® Luer Lock Solo	4617207V							N/A
Omnifix® Luer Lock Solo	4617207V-03							N/A
Omnifix® Luer Lock Solo	4617304F							N/A
Omnifix® Luer Lock Solo	4617509F							N/A
Omnifix® Luer Lock Solo	4617509F-03							N/A
Omnifix® Luer Lock Solo	4617510F-06	4039239000000207022	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670002S-01	403923900000076936	G1 012974 0607	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Sterican® Safety Needle	4670005S-01		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000076834	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican®	4650034							N/A
Sterican®	4657500							N/A
Sterican®	4657519							N/A
Sterican®	4657527							N/A
Sterican®	4657543							N/A
Sterican®	4657624							N/A
Sterican®	4657640							N/A
Sterican®	4657667							N/A
Sterican®	4657675							N/A
Sterican®	4657683							N/A
Sterican®	4657705							N/A
Sterican®	4657799							N/A
Sterican®	4657853							N/A
Sterican®	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Sterican®	4665643							N/A
Sterican®	4665791							N/A
Sterican®	4667093							N/A
Sterican®	4667123							N/A
Sterican®	9180109							N/A
Sterican®	9180117							N/A
Sterican®	9186158							N/A
Sterican®	9186166							N/A
Sterican®	9186174							N/A
Sterican®	9186182							N/A
Injekt®-H Luer Duo	9166297	40392390000007742X	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022C	40392390000007752Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022UA							N/A
Injekt® Luer Duo	4645022V							N/A
Injekt® Luer Duo	4645057C							N/A
Injekt® Luer Duo	4645057UA							N/A
Injekt® Luer Duo	4645057V							N/A
Injekt® Luer Duo	4645065C							N/A
Injekt® Luer Duo	4645103C							N/A
Injekt® Luer Duo	4645103UA							N/A
Injekt® Luer Duo	4645103V							N/A
Injekt® Luer Duo	4645200C							N/A
Injekt® Luer Duo	4645200UA							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Injekt® Luer Duo	4645200V							N/A
Injekt® Luer Duo	4647220							N/A
Injekt®-F Luer Duo	9166033V							N/A
Sterican® Safety Needle	4670030SBR	403923900000076936	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670053SBR		NB0123					N/A
Contiplex® D	4898323	40392390000008522S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898325							N/A
Contiplex® D	4898305							N/A
Contiplex® D	4898308							N/A
Contiplex® D	4898311							N/A
Contiplex® D	4898335							N/A
Contiplex® D NRFit®	4898305NR							N/A
Contiplex® D NRFit®	4898335NR							N/A
Contiplex® D NRFit®	4898311NR							N/A
Contiplex® D NRFit®	4898323NR							N/A
Contiplex® D NRFit®	4898325NR							N/A
Contiplex® D	4895819NCN							N/A
Contiplex® D	4894235NCN							N/A
Contiplex® D	4894391NCN							N/A
Contiplex® D	4898205	40392390000008532U	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898211							N/A
Contiplex® D	4898235							N/A
Contiplex® C	4898115	403923900000085000	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® C	4898130		NB0123					N/A
Contiplex® C NRFit®	4898115NR							N/A
Contiplex® C NRFit®	4898130NR							N/A
Ultraplex® 360	4892603-01	40392390000008552Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Ultraplex® 360	4892603CN							N/A
Ultraplex® 360 NRFit®	4892603NR-01							N/A
Ultraplex® 360	4892605-01							N/A
Ultraplex® 360	4892605CN							N/A
Ultraplex® 360 NRFit®	4892605NR-01							N/A
Ultraplex® 360	4892608-01							N/A
Ultraplex® 360	4892608CN							N/A
Ultraplex® 360 NRFit®	4892608NR-01							N/A
Ultraplex® 360	4892610-01							N/A
Ultraplex® 360	4892610CN							N/A
Ultraplex® 360 NRFit®	4892610NR-01							N/A
Ultraplex® 360	4892615-01							N/A
Ultraplex® 360	4892615CN							N/A
Ultraplex® 360 NRFit®	4892615NR-01							N/A
Stimuplex® D	4892105	40392390000008502N	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® D	4892105-23							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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Stimuplex® D	4892208							N/A
Stimuplex® D	4892208-23							N/A
Stimuplex® D NRFit®	4892208NR							N/A
Stimuplex® Ultra 360®	4892503-01	40392390000008512Q	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

Effective

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

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

Schedule of Devices

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

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)			Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Stimuplex® Ultra 360®	4892503-03		NB0123					N/A
Stimuplex® Ultra 360®	4892503-04							N/A
Stimuplex® Ultra 360®	4892503-20							N/A
Stimuplex® 360®	4892503CN							N/A
Stimuplex® Ultra 360® NRFit®	4892503NR-01							N/A
Stimuplex® Ultra 360®	4892505-01							N/A
Stimuplex® Ultra 360®	4892505-03							N/A
Stimuplex® Ultra 360®	4892505-04							N/A
Stimuplex® Ultra 360®	4892505-20							N/A
Stimuplex® 360®	4892505CN							N/A
Stimuplex® Ultra 360® NRFit®	4892505NR-01							N/A
Stimuplex® Ultra 360®	4892508-01							N/A
Stimuplex® Ultra 360®	4892508-03							N/A
Stimuplex® Ultra 360®	4892508-04							N/A
Stimuplex® Ultra 360®	4892508-20							N/A
Stimuplex® 360®	4892508CN							N/A
Stimuplex® Ultra 360® NRFit®	4892508NR-01							N/A
Stimuplex® Ultra 360®	4892510-01							N/A
Stimuplex® Ultra 360®	4892510-03							N/A
Stimuplex® Ultra 360®	4892510-04							N/A

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

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Schedule of Devices

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000044ZG	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617014		NB0123					N/A
Omnifix® Lock	4617021							N/A
Omnifix® Lock	4617508F-01							N/A
Original Perfusor® Syringe 20 ml	8728615	403923900000077939	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728615C		NB0123					N/A
Original Perfusor® Syringe 20 ml	8728623	40392390000029923R	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728623C		NB0123					N/A
Original Perfusor® Syringe 50 ml	8728810F-04							N/A

Effective

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

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Schedule of Devices

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

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)			Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Original Perfusor® Syringe 50 ml	8728810F-06							8728810F
Original Perfusor® Syringe 50 ml	8728810F-20							N/A
Original Perfusor® Syringe 50 ml	8728844F-04							N/A
Original Perfusor® Syringe 50 ml	8728844F-06	403923900000077939	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	8728844F
Original Perfusor® Syringe 50 ml	8728844F-20							N/A
Original Perfusor® Syringe 50 ml	8728852F-04							N/A
Original Perfusor® Syringe 50 ml	8728852F-06	40392390000029923R	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728852F-20							N/A
Original Perfusor® Syringe 50 ml	8728861F-04							N/A
Original Perfusor® Syringe 50 ml	8728861F-06	403923900000207124	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728861F-20							N/A
Original Perfusor® Syringe 50 ml	8728845F-01							N/A
Original Perfusor® Syringe 50 ml	8728845F-01	40392390000007802S	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450100	40392390000009993R	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450120							N/A
Cystofix®	4450130							N/A

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

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Effective

Schedule of Devices

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cystofix®	4450150							N/A
Cystofix®	4450160							N/A
Cystofix®	4450170							N/A
Cystofix®	4450180							N/A
Cystofix®	4450200	4039239000001000Z3	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450220		NB0123					N/A
Cystofix SG	4450410	4039239000001002Z7	G1 022239 0080	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix SG	4450412		NB0123 B.BRAUN MEDICAL SAS					N/A
Cystofix SG	4450414							N/A
Cystofix SG	4450416							N/A
Cystofix	4450010	4039239000001001Z5	G1 022239 0080	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450012		NB0123 B.BRAUN MEDICAL SAS		TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)		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	40392390000009272Y	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasco® OP Powdered	6031525		NB0123					N/A
Vasco® OP Powdered	6031532							N/A

Effective

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

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Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10

Schedule of Devices

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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasco® OP Free	9208364							N/A
Drainobag® Connection Tube Bayonet	5524913	40392390000008052H	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	U2170701
Filter Needle	415040	4039239000000290000	G2S 012974 0457 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	4550404
Filter Hub	418021							4551001
Filter Straw	415020							4550200
Filter Straw	415021							4550250
Sterifix® Filter Straw 4"	339171							4550200N
Sterifix® Filter Straw 1.75"	339170							4550250N
Sterifix® Filter Needle 1.5"	339169							4550404N

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

Effective

Document History

Version	Description of Change
1.0	Initial version

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

Effective

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

UserName: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: Wednesday, 15 May 2024, 15:10 W. Europe Daylight Time
Meaning: Document signed as Author

=====

UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Wednesday, 15 May 2024, 15:24 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 15 May 2024, 16:49 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 15 May 2024, 17:22 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Arico, Mareike (sommrde)
Title: HC-QM - Head of QM active MD/ Head of Regulatory Affairs CoE AIS
Date: Wednesday, 15 May 2024, 21:34 W. Europe Daylight Time
Meaning: Approve Document

=====

Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10 Initiator: Anja Mai

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

UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
Date: Thursday, 16 May 2024, 07:36 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Thursday, 16 May 2024, 08:19 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Meyer, Frank (meyefrde)
Title: HC-QM-DE08 Vice President QM Applications Hospital Care
Date: Thursday, 16 May 2024, 09:09 W. Europe Daylight Time
Meaning: Final Release of the Document

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MANUFACTURER'S DECLARATION

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	B. Braun Melsungen AG
Manufacturer address and contact details	Carl-Braun Straße 1 34212 Melsungen GERMANY
Single Registration Number (SRN) (if available)	DE-MF-000000201

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Notified body name (if applicable)	TÜV SÜD Product Service GmbH	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	0123	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	(1) G1 012974 0607; (2) G1 019717 0032; (3) G1 022239 0080; (4) G2S 012974 0457	<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	(1) 2024-05-26; (2) 2024-05-26; (3) 2024-05-26; (4) 2024-05-26	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	2028-12-31	<input checked="" type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above or in the attached schedule
- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- ☐ Expired *before* 20 March 2023:
- ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- ☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Quality Management System (QMS)

Choose one applicable statement:

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

➤ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

	Quality Management	Regulatory Affairs
Full Company Name	B. Braun Melsungen AG	B. Braun Melsungen AG
Location & Date	Melsungen, 2024-04-15	Melsungen, 2024-04-15
Signature	See electronic signature	See electronic signature
Print Name	(1) Thomas Brand; (2) Mareike Arico; (3) Dr. Frank Ritz	(4) Dr. Stefan Seidel; (5) Malte Loh; (6) Dr. Joachim Buenger
Title	(1) Vice President Quality Management for non-active Medical Devices; (2) Head of Quality Management Active Medical Devices/ Head of	(4) Head of Regulatory Affairs CoE Infusion & Pain Therapy; (5) Senior Manager Regulatory



	Regulatory Affairs CoE AIS; (3) Vice President QM Pharma; Hospital Care Division	Affairs; (6) Director Template & Submission Mgmt
Contact Details (at least email)	BBMAG-HC@bbraun.com	BBMAG-HC@bbraun.com
Version of document	Version 1.0	

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Perfusor® compactplus	8717030	403923900000038ZM	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus	8717050	40392390000005352B	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
OnlineSuite	876100	40392390000005552H	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Perfusor®	8719030	40392390000007562V	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Spaceplus Infusomat®	8719050	40392390000007552T	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® compactplus P	8717070	40392390000007492Y	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4116011F	4039239000000039ZP	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617006	4039239000000044ZG	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	932M04SE	403923900000018743B	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican fine	931M08SE		NB0123					N/A
Drainobag® 600 V	5523606	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drug Library Manager Spaceplus	876203	403923900000169539	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drug Library Manager Spaceplus	876209	403923900000169539	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FR29914	403923900000249638	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
GLYCINE 1,5 % B. BRAUN	FREU914							N/A
GLYCINE 1,5 % B. BRAUN	FREU934							N/A
GLYCINE 1,5 % B. BRAUN	FREU954							N/A
GLYCINE 1,5 % B. BRAUN	FREU974							N/A
NaCl 0,9 % B. BRAUN	FREU850	403923900000250128	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	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	40392390000026312N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	3637006							N/A
NaCl 0,9 % B. BRAUN	0069414E							N/A
NaCl 0,9 % B. BRAUN	3521360							N/A
NaCl 0,9 % B. BRAUN	3570120							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
NaCl 0,9 % B. BRAUN	3570130							N/A
NaCl 0,9 % B. BRAUN	3570140							N/A
NaCl 0,9 % B. BRAUN	0066570E							N/A
NaCl 0,9 % B. BRAUN	3521370							N/A
NaCl 0,9 % B. BRAUN	3570150							N/A
NaCl 0,9 % B. BRAUN	3570160							N/A
NaCl 0,9 % B. BRAUN	3570170							N/A
NaCl 0,9 % B. BRAUN	0066569E							N/A
NaCl 0,9 % B. BRAUN	3570110							N/A
Vitulia	450268	40392390000025022A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
NaCl 0,9 % B. BRAUN	3570370							N/A
NaCl 0,9 % B. BRAUN	3570380							N/A
NaCl 0,9 % B. BRAUN	3570390							N/A
NaCl 0,9 % B. BRAUN	391860							N/A
NaCl 0,9 % B. BRAUN	3570410							N/A
NaCl 0,9 % B. BRAUN	3570420							N/A
NaCl 0,9 % B. BRAUN	3570460	40392390000026302L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
NaCl 0,9 % B. BRAUN	3570470		NB0123					N/A
NaCl 0,9 % B. BRAUN	3570480							N/A
RINGER B. BRAUN	FREU864	40392390000025062J	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	FREU924		NB0123					FREU920
RINGER B. BRAUN	FREU944							N/A
RINGER B. BRAUN	FREU964							N/A
RINGER B. BRAUN	FREU984							N/A
RINGER B. BRAUN	3570000	40392390000026342U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
RINGER B. BRAUN	3570010		NB0123					N/A
RINGER B. BRAUN	3570020							N/A
RINGER B. BRAUN	3570030							N/A
RINGER B. BRAUN	3570040							N/A
RINGER B. BRAUN	3570050							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
RINGER B. BRAUN	3570060							N/A
RINGER B. BRAUN	3570611	40392390000026322Q	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570490
RINGER B. BRAUN	3570610							3570500
RINGER B. BRAUN	3570614							3570510
RINGER B. BRAUN	3570612							3570520
RINGER B. BRAUN	3570613	40392390000026332S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	3570530
Aqua B. Braun	FREU812	40392390000024973A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	FREU852							N/A
Aqua B. Braun	FREU912							N/A
Aqua B. Braun	FREU932							N/A
Aqua B. Braun	387872	40392390000026272X	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	387873		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Aqua B. Braun	387874							N/A
Aqua B. Braun	442464							N/A
Aqua B. Braun	442465							N/A
Aqua B. Braun	442466							N/A
Sterile Water for Irrigation	3637011							N/A
Aqua B. Braun	3521380	403923900000262933	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Aqua B. Braun	3521390							N/A
Aqua B. Braun	3553949							N/A
Aqua B. Braun	3553957							N/A
Aqua B. Braun	0065729E							N/A
Aqua B. Braun	0066571E							N/A
Aqua B. Braun	0069415E							N/A
Aqua B. Braun	0082423E							N/A
Aqua B. Braun	0082479E							N/A
Sterile Water for Irrigation	3637007							N/A
Perifix® Catheter Connector	4513800	403923900000238732	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Catheter Connector	4513801							N/A
Perifix® Catheter Connector NRFit	4513800N-01							N/A
Perifix® Catheter Connector NRFit	4513801N-01							N/A
Infusomat® Space	8713050	40392390000007462S	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Space P	8713070	40392390000007472U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Perfusor® Space	8713030	40392390000007482W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Enteroport® plus	8710355	40392390000007452Q	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200	40392390000008622V	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700200-20							N/A
Infusomat® Plus Line SafeSet	8700210							N/A
Infusomat® Plus Line	8700310							N/A
Infusomat® Plus Line	8700310-20							N/A
Infusomat® Plus Line	8700310CN							N/A
Cyto-Set® Infusomat® Space	8250414SP	40392390000007832Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set® Infusomat® Space	835414SP							N/A
Cyto-Set® Infusomat® Space	835817SP							N/A
Cyto-Set® Infusomat® Space	835820SP							N/A
Cyto-Set® Infusomat® Space	835917SP							N/A
Cyto-Set® Infusomat® Space	835920SP							N/A
Cyto-Set® Infusomat® plus	8700420							N/A
Cyto-Set® Infusomat® plus	8700430							N/A
Cyto-Set® Infusomat® plus	8700440							N/A
Cyto-Set® Infusomat® plus	8700450							N/A
Cyto-Set® Infusomat® plus	8700460							N/A
Cyto-Set® Infusomat® plus	8700470							N/A
Cyto-Set® Infusomat® plus	8700480							N/A
Cyto-Set® Infusomat® plus	8700490							N/A
Cyto-Set® Line	A2581NF	403923900000078432	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Line	A2582NF		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cyto-Set® Mix	A2900N							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	4039239000008602R	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® A	4894539							N/A
Stimuplex® A	4894367							N/A
Stimuplex® A	4894502							N/A
Stimuplex® A	4894375							N/A
Stimuplex® A	4894260							N/A
Stimuplex® A	4894278							N/A
Stimuplex® A	4894278NR							N/A
Stimuplex® A	4894375NR							N/A
Stimuplex® A	4894260NR							N/A
Stimuplex® A	4894367NR							N/A
Stimuplex® A	4894539NR							N/A
Stimuplex® A	4894502NR							N/A
Stimuplex® A	4894251 NR							N/A
Easypump® II LT 60-12	4540002	40392390000023452J	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Easypump® II LT 60-12	4540002-07							N/A
Easypump® II LT 60-12	4540002-20							N/A
Easypump® II LT 500-12.5	4540003							N/A
Easypump® II LT 500-12.5	4540003-07							N/A
Easypump® II LT 500-12.5	4540003-20							N/A
Easypump® II LT 80-16	4540004							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II LT 80-16	4540004-07							N/A
Easypump® II LT 80-16	4540004-20							N/A
Easypump® II LT 125-25	4540006							N/A
Easypump® II LT 125-25	4540006-07							N/A
Easypump® II LT 125-25	4540006-20							N/A
Easypump® II LT 270-27	4540008							N/A
Easypump® II LT 270-27	4540008-07							N/A
Easypump® II LT 270-27	4540008-20							N/A
Easypump® II LT 60-30	4540010							N/A
Easypump® II LT 60-30	4540010-07							N/A
Easypump® II LT 60-30	4540010-20							N/A
Easypump® II LT 120-30	4540012							N/A
Easypump® II LT 120-30	4540012-07							N/A
Easypump® II LT 120-30	4540012-20							N/A
Easypump® II LT 400-40	4540014							N/A
Easypump® II LT 400-40	4540014-07							N/A
Easypump® II LT 400-40	4540014-20							N/A
Easypump® II LT 100-50	4540016							N/A
Easypump® II LT 100-50	4540016-07							N/A
Easypump® II LT 100-50	4540016-20							N/A
Easypump® II LT 270-54	4540018							N/A

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II LT 270-54	4540018-07							N/A
Easypump® II LT 270-54	4540018-20							N/A
Easypump® II LT 400-80	4540022							N/A
Easypump® II LT 400-80	4540022-07							N/A
Easypump® II LT 400-80	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Easypump® II ST 50-1	4540044-07							N/A
Easypump® II ST 50-1	4540044-20							N/A
Easypump® II ST 100-1	4540046							N/A
Easypump® II ST 100-1	4540046-07							N/A
Easypump® II ST 100-1	4540046-20							N/A
Easypump® II ST 250-1	4540048							N/A
Easypump® II ST 250-1	4540048-07							N/A
Easypump® II ST 250-1	4540048-20							N/A
Easypump® II ST 250-1,5	4540050							N/A
Easypump® II ST 250-1,5	4540050-07							N/A
Easypump® II ST 250-1,5	4540050-20							N/A
Easypump® II ST 400-2	4540052							N/A
Easypump® II ST 400-2	4540052-07							N/A
Easypump® II ST 400-2	4540052-20							N/A
Easypump® II ST 500-2	4540054							N/A
Easypump® II ST 500-2	4540054-07							N/A
Easypump® II ST 500-2	4540054-20							N/A
Easypump® II ST 100-2	4540056							N/A
Easypump® II ST 100-2	4540056-07							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000085836	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	4505000
Spinal Introducer	4500059-13		NB0123					4500059
Contiplex® S 360	4898650CN	40392390000008542W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® S 360	4898610CN		NB0123					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	4039239000000238834	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Perifix® Filter NRFit	4515501N-01		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® S Ultra 360® NRFit®	4898650NR-27	40392390000008542W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® S Ultra 360® NRFit®	4898610NR-27							N/A
Contiplex® S Ultra 360® NRFit®	4898615NR-27							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898704NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898705NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898710NR-01							N/A
Contiplex® Tuohy Ultra 360® NRFit®	4898715NR-01							N/A
Contiplex® Tuohy Ultra 360®	4898704-01							N/A
Contiplex® Tuohy Ultra 360®	4898705-01							N/A
Contiplex® Tuohy Ultra 360®	4898710-01							N/A
Contiplex® Tuohy Ultra 360®	4898715-01							N/A
Contiplex® Tuohy Ultra 360®	4898704-27							N/A
Contiplex® Tuohy Ultra 360®	4898705-27							N/A
Contiplex® Tuohy Ultra 360®	4898710-27							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® Tuohy Ultra 360®	4898715-27							N/A
Discofix®	4099117	40392390000007582Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix®	4095111		NB0123					N/A
Discofix®	4095120							N/A
Discofix®	4095146							N/A
Discofix®	4095111IN							N/A
Discofix®	409511CN							N/A
Discofix®	409512CN							N/A
Discofix®	16466							N/A
Discofix®	4098102							N/A
Discofix®	409810CN							N/A
Discofix®	4098218							N/A
Discofix®	409821CN							N/A
Discofix®	4098501							N/A
Discofix®	4098234							N/A
Discofix®	4098080							N/A
Discofix®	4055150							N/A
Discofix®	4055145							N/A
Discofix®	4055146							N/A
Discofix®	4055149							N/A
Discofix®	4055147							N/A
Discofix®	4055148							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix®	4099010							N/A
Discofix®	4095210							15809
Nutritub® ENFit® intestinal	9246605	40392390000029463J	G1 019717 0032 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246584
			9246586					
Nutritub® ENFit® intestinal	9246604		B. Braun Avitum Italy S.p.A.					9246576
								9246578
Nutritub® Gastral Basic ENFit®	9246603	40392390000008172Q	G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	9246519
Nutritub® Gastral Basic ENFit®	9246602		NB0123					9246518
Nutritub® Gastral Basic ENFit®	9246601		B. Braun Avitum Italy S.p.A.					9246516
								9246550
Nutritub® Gastral Basic ENFit®	9246600							9246515
								9246592
Nutritub® Gastral Basic ENFit®	9246599							9246514
Nutritub® Gastral Basic ENFit®	9246598							9246513
Nutritub® Gastral Basic ENFit®	9246597		9246541					
			9246543					

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Nutritub® Gastral Basic ENFit®	9246596							9246512
Nutritub® Gastral Basic ENFit®	9246595							9246517 9246525 9246533 9246535
Nutritub® Gastral Basic ENFit®	9246594							9246509 9246511
Nutritub® Gastral Basic ENFit®	9246593							9246508
Infusomat® Space Line	8250832SP							8250833SP
Infusomat® Space Line	8250834SP		NB0123		TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	8250835SP
IN-Stopper	4238010	40392390000028583L	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
IN-Stopper	4238011		NB0123					N/A
Combi-Stopper	4495101	40392390000008112C	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495152		NB0123					N/A
Combifix Adapter	5206634	40392390000008122E	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Combifix Adapter	5206642		NB0123					N/A
Original Perfusor® Line	87229910	40392390000008702U	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
			NB0123					
Pleurofix® No. 1	4461002	40392390000007902V	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleurofix® No. 2	4461037		NB0123					N/A
Seldinger Introducer Needle	4206096	40392390000007442N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Seldinger Introducer Needle	4206100		NB0123					N/A
Injekt® 40 Duo	9166432C	4039239000000121823	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® 40 Duo	9166432V		NB0123					N/A
Introcan Safety® 3	4251127-01	40392390000007652W	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety® 3	4251127-03		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Introcan Safety® 3	4251134-01							N/A
Introcan Safety® 3	4251134-03							N/A
Introcan Safety® 3	4251134-04							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Infusomat® Space Line	8700036SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line	8700435SP							N/A
Infusomat® Space Line SafeSet	8701148SP							N/A
Infusomat® Space Line	8270066SP-01	403923900000086635	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8270066SP
Infusomat® Space Line	8270066SP-26							N/A
Infusomat® Plus Line	8700350-01	403923900000086533	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-26							N/A
Enteroport® ENFit® Set		4039239000000263732	G1 019717 0032	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	8721748

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set®	8250266	40392390000007832Y	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Cyto-Set®	8250366							N/A
ProSet Cyto-Set®	8250370							N/A
ProSet Cyto-Set® 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

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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Cyto-Set® Mix	4188925							N/A
ProSet Cyto-Set® Mix	4188926							N/A
ProSet Cyto-Set® Pump Adapter	4182704	403923900000078534	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cyto-Set® Pump Adapter	A1673SO		NB0123					N/A
Dosifix®	4037011	40392390000008192U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Dosifix®	4037012		NB0123					N/A
Dosifix®	4037013							N/A
Dosifix®	4037032							N/A
Dosifix®	4037031	40392390000008202D	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					
Heidelberger Extension Tubing	4033809	403923900000078636	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4034589		NB0123					N/A
Heidelberger Extension Tubing	4038703							N/A
Heidelberger Extension Tubing	4055128							N/A
Heidelberger Extension Tubing	4055136							N/A
Extension Line, Type: Heidelberg	4097130							N/A
Extension Line, Type: Heidelberg	4097173							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Introcan® Certo	4055764	40392390000007612N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan® Certo	4251300							N/A
Introcan® Certo	4251318							N/A
Introcan® Certo	4251326							N/A
Introcan® Certo	4251334							N/A
Introcan® Certo	4251342							N/A
Introcan® Certo	4251350							N/A
Introcan® Certo	4251369							N/A
Introcan®	4252071B							N/A
Introcan®	4252098B							N/A
Introcan®	4252110B							N/A
Introcan®	4252136B							N/A
Introcan®	4252160B							N/A
Introcan®	4252217B							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan®	4252322B							N/A
Introcan®-W Certo	4253302							N/A
Introcan®-W Certo	4253310							N/A
Introcan®-W Certo	4253329							N/A
Introcan®-W Certo	4253337							N/A
Introcan®-W Certo	4253345							N/A
Introcan®-W Certo	4253353							N/A
Introcan®-W Certo	4253361							N/A
Introcan®-W	4254074B							N/A
Introcan®-W	4254090B							N/A
Introcan®-W	4254112B							N/A
Introcan®-W	4254139B							N/A
Introcan®-W	4254171B							N/A
Introcan®-W	4254210B							N/A
Introcan®-W	4254325B							N/A
Discofix® C Safeflow	16494CCN	40392390000007602L	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C Safeflow	16495CCN							N/A
Discofix® C Safeflow	16501CCN							N/A
Discofix® C Safeflow	16500CCN							N/A
Discofix® C Safeflow	16540CCN							N/A
Discofix® C Safeflow	16520CCN							N/A
Intrapur®-Neonat	4099451	40392390000008082P	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrapur®	4093216							N/A
Sterifix®	4184637							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000075933	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16540C							N/A
Discofix® C	16494C							N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Discofix® C	16720C							N/A
Discofix® C	16520CSF							N/A
Discofix® C	16520C							N/A
Discofix® C	16701C							N/A
Discofix® C	16496C							N/A
Discofix® C	16501CSF-1							N/A
Discofix® C	RU16496C							N/A
Discofix® C	RU16495C							N/A
Discofix® C	CN16496C							N/A
Discofix® C	RU16494C							N/A
Discofix® C	EC16494C							N/A
Discofix® C	CN16494C							N/A
Discofix® C	16611C							N/A
Discofix® C	16608C							N/A
Discofix® C	16600C							N/A
Discofix® C	16501CSF							N/A
Pleuracan®	4462556	40392390000007922Z	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Pleuracan® B	4462505		NB0123					N/A
Pleuracan® Back-Check Valve	4462564	403923900000079333	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600	5523682	4039239000000281736	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16700C	403923900000075933	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Discofix® C	16500C		NB0123					N/A
Discofix® C	16495C							N/A
Discofix® C	16560CSF							N/A
Discofix® C	16901C							N/A
Discofix® C	16615C							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000026953G	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Heidelberger Extension Tubing	4052197							N/A
Heidelberger Extension Tubing	4052197H							N/A
Introcan Safety®	4251601-01	40392390000007632S	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Introcan Safety®	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan Safety®	4252519-03							N/A
Introcan Safety®	4252519-04							N/A
Introcan Safety®	4252520-01							N/A
Introcan Safety®	4252527-01							N/A
Introcan Safety®	4252527-03							N/A
Introcan Safety®	4252535-01							N/A
Introcan Safety®	4252535-03							N/A
Introcan Safety®	4252535-04							N/A
Introcan Safety®	4252543-01							N/A
Introcan Safety®	4252551-01							N/A
Introcan Safety®	4252551-03							N/A
Introcan Safety®	4252551-04							N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Introcan Safety® W	4253604-01							N/A
Introcan Safety® W	4253604-03							N/A
Introcan Safety® W	4253604-04							N/A
Introcan Safety® W	4253604JP							N/A
Introcan Safety® W	4253612-01							N/A
Introcan Safety® W	4253612-03							N/A
Introcan Safety® W	4253612-04							N/A
Introcan Safety® W	4253639-01							N/A
Introcan Safety® W	4253639-03							N/A
Introcan Safety® W	4253639JP							N/A
Introcan Safety® W	4253639-04							N/A
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000008082P	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Intrapur®	4183925							N/A
ProSet Intrapur®	4183926							N/A
ProSet Intrapur®	4183927							N/A
ProSet Intrapur®	4183948							N/A
ProSet Intrapur®	4183949							N/A
ProSet Intrapur®	4184004							N/A
ProSet Intrapur®	4184006							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Intrapur®	4184007							N/A
ProSet Intrapur®	4184008							N/A
ProSet Intrapur®	4098725							N/A
ProSet Intrapur®	4081002							N/A
ProSet Sterifix® Neonat	4099265							N/A
ProSet Intrapur®	4187822							N/A
ProSet Intrapur®	4184001							N/A
ProSet Intrapur®	4183255							N/A
ProSet Intrapur®	4183245							N/A
ProSet Intrapur®	4183240							N/A
ProSet Intrapur®	4180351							N/A
ProSet Intrapur®	4180350							N/A
ProSet Discofix® C	4188960	403923900000075933	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Discofix® C	4188959							N/A
ProSet Discofix® C	4188957							N/A
ProSet Discofix® C	4188105							N/A
ProSet Discofix® C	4188071							N/A
ProSet Discofix® C	4187954							N/A
ProSet Discofix® C	4187826							N/A
ProSet Discofix® C	4187202							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4187199							N/A
ProSet Discofix® C	4187032							N/A
ProSet Discofix® C	4184963							N/A
ProSet Discofix® C	4184491							N/A
ProSet Discofix® C	4184246							N/A
ProSet Discofix® C	4184030							N/A
ProSet Discofix® C	4184022							N/A
ProSet Discofix® C	4182635							N/A
ProSet Discofix® C	4181234							N/A
ProSet Discofix® C	4180965							N/A
ProSet Discofix® C	4086481							N/A
ProSet Discofix® C	4085230							N/A
ProSet Discofix® C	4085213							N/A
ProSet Discofix® C	4187203							N/A
ProSet Discofix® C	4182308							N/A
ProSet Discofix® C	4187527							N/A
ProSet Discofix® C	4180437							N/A
ProSet Discofix® C	4183088							N/A
ProSet Discofix® C	4088698							N/A
ProSet Discofix® C	4084792							N/A
ProSet Discofix® C	4085300SF							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4085086							N/A
ProSet Discofix® C	4181027							N/A
ProSet Discofix® C	4184005							N/A
ProSet Discofix® C	4187291							N/A
ProSet Discofix® C	4183312							N/A
ProSet Discofix® C	4185366							N/A
ProSet Discofix® C	4185927							N/A
ProSet Discofix® C	4188188							N/A
ProSet Discofix® C	4086482							N/A
ProSet Discofix® C	4184327							N/A
ProSet Discofix® C	4180439							N/A
ProSet Discofix® C	4180306							N/A
ProSet Discofix® C	4182944							N/A
ProSet Discofix® C	4083255							N/A
ProSet Discofix® C	4187911							N/A
ProSet Discofix® C	4187823							N/A
ProSet Discofix® C	4187878							N/A
ProSet Discofix® C	4085168							N/A
ProSet Discofix® C	4189821							N/A
ProSet Discofix® C	4188958							N/A
ProSet Discofix® C	4187213							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4187880							N/A
ProSet Discofix® C	4083254							N/A
ProSet Discofix® C	4189847							N/A
ProSet Discofix® C	4188198							N/A
ProSet Discofix® C	4183510							N/A
ProSet Discofix® C	4187033							N/A
ProSet Discofix® C	4188072							N/A
ProSet Discofix® C	4183787							N/A
ProSet Discofix® C	4180678							N/A
ProSet Discofix® C	4180679							N/A
ProSet Discofix® C	4187879							N/A
ProSet Discofix® C	4185928							N/A
ProSet Discofix® C	4086879							N/A
ProSet Discofix® C	4188047							N/A
ProSet Discofix® C	4189839							N/A
ProSet Discofix® C	4183852							N/A
ProSet Discofix® C	4185985							N/A
ProSet Discofix® C	4085450SF							N/A
ProSet Discofix® C	4089464							N/A
ProSet Discofix® C	4182737							N/A
ProSet Discofix® C	4180300							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4183777							N/A
ProSet Discofix® C	4185972							N/A
ProSet Discofix® C	4184521							N/A
ProSet Discofix® C	4182652							N/A
ProSet Discofix® C	4184483							N/A
ProSet Discofix® C	4087930							N/A
ProSet Discofix® C	4184817							N/A
ProSet Discofix® C	4187391							N/A
ProSet Discofix® C	4182720							N/A
ProSet Discofix® C	4185821N							N/A
ProSet Discofix® C	4085434SF							N/A
ProSet Discofix® C	4188225							N/A
ProSet Discofix® C	4186580							N/A
ProSet Discofix® C	4186579							N/A
ProSet Discofix® C	4085500SF							N/A
ProSet Discofix® C	4181778							N/A
ProSet Discofix® C	4180459							N/A
ProSet Discofix® C	4188510							N/A
ProSet Discofix® C	4180438							N/A
ProSet Discofix® C	4086945							N/A
ProSet Discofix® C	4187898							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Discofix® C	4185021							N/A
ProSet Discofix® C	4187529							N/A
ProSet Discofix® C	4088520							N/A
ProSet Discofix® C	4181028							N/A
ProSet Discofix® C	4182638							N/A
ProSet Discofix® C	4088699							N/A
ProSet Discofix® C	4180120							N/A
ProSet Discofix® C	4180677							N/A
ProSet Discofix® C	4182633							N/A
ProSet Discofix® C	4182639							N/A
ProSet Discofix® C	4187838							N/A
ProSet Discofix® C	4084510							N/A
ProSet Discofix® C	4182651							N/A
ProSet Discofix® C	4187834							N/A
ProSet Discofix® C	4180445							N/A
ProSet Discofix® C	4083777							N/A
ProSet Discofix® C	4187308							N/A
ProSet Discofix® C	4184424							N/A
ProSet Discofix® C	4182182							N/A
Vasofix® Braunüle®	4268091B	40392390000007622Q	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasofix® Braunüle®	4268113B		NB0123					N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasofix® Braunüle®	4268130B							N/A
Vasofix® Braunüle®	4268156B							N/A
Vasofix® Braunüle®	4268172B							N/A
Vasofix® Braunüle®	4268210B							N/A
Vasofix® Braunüle®	4268334B							N/A
Vasofix® Certo	4269071							N/A
Vasofix® Certo	4269098							N/A
Vasofix® Certo	4269110							N/A
Vasofix® Certo	4269136							N/A
Vasofix® Certo	4269152							N/A
Vasofix® Certo	4269179							N/A
Vasofix® Certo	4269217							N/A
Vasofix® Certo	4269225							N/A
Vasofix® Certo	4269330							N/A
Extension Line	4051807	40392390000007893C	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Extension Line	4054393		NB0123					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

Effective

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000007642U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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
Vasofix® Safety	4268210S-03							N/A
Vasofix® Safety	4268334S-01							N/A

Effective

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

Effective

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasofix® Safety	4269179S-03							N/A
Vasofix® Safety	4269179SIN							N/A
Vasofix® Safety	4269179S-20							N/A
Vasofix® Safety	4269217S-01							N/A
Vasofix® Safety	4269217S-03							N/A
Vasofix® Safety	4269217S-20							N/A
Vasofix® Safety	4269225S-01							N/A
Vasofix® Safety	4269225S-03							N/A
Vasofix® Safety	4269225S-20							N/A
Vasofix® Safety	4269330S-01							N/A
Vasofix® Safety	4269330S-03							N/A
Vasofix® Safety	4269330S-20							N/A
ProSet Spiral Line	4091728	40392390000007893C	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Spiral Line	4091736							N/A
ProSet Spiral Line	4091740							N/A
ProSet Spiral Line	4091752							N/A
ProSet Spiral Line	4092539							N/A
ProSet Spiral Line	4092937							N/A
ProSet Spiral Line	4092945							N/A
ProSet Spiral Line	4092953							N/A
ProSet Spiral Line	4092961							N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Extension Line	4095251							N/A
ProSet Extension Line	4097531							N/A
Extension Line	4097572							N/A
ProSet Spiral Line	4099362							N/A
ProSet Extension Line	4185841							N/A
ProSet Extension Line	4185842							N/A
ProSet Spiral Line	4187466							N/A
ProSet Spiral Line	4187467							N/A
ProSet Spiral Line	4187468							N/A
ProSet Spiral Line	4187469							N/A
ProSet Spiral Line	4188080							N/A
Extension Line	9500049							N/A
Extension Line	9500057							N/A
Extension Line	9500065							N/A
Infusomat@plus Line SafeSet	8700390	40392390000014782X	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat@plus Line SafeSet	8700391		NB0123					N/A
Infusomat@plus Line SafeSet	8700392	403923900000259235	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Space Line SafeSet	8700140SP	40392390000014772V	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Space Line SafeSet	8700141SP		NB0123					N/A
Infusomat® Space Line SafeSet	8700142SP	403923900000259133	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4060369L	40392390000007812U	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4060407		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® SafeSet	4063005							N/A
Intrafix® SafeSet	4063006							N/A
Drainobag® Basse Pression	5524237	403923900000281736	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 300	5522390							N/A
Drainobag® 150	5523753							N/A
Drainobag® Lock 150	5523761							N/A
Drainobag® Lock 150	55237611							N/A
Drainobag® Lock 400	5523602							U2000600
Drainobag® 600 V	5523605							N/A
Drainobag® Lock 600 V	5523648	40392390000007973B	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 V	5523649							N/A
Drainobag® Basse Pression TL	5524210							N/A
Drainobag® 300 V	5522322							N/A
Drainobag® Lock 300 V	5522340							N/A
Drainobag® Lock 300 V	55223401							N/A
Drainobag® 150 V	5523702							N/A
Drainobag® 150 VL	5523710							N/A
Drainobag® Lock 150 V	5523729							N/A
Drainobag® Lock 150 VL	5523737							N/A
Drainobag® Lock 150 VL	55237371							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drainobag® 400 V	5523601							U2000500
Drainobag® Lock 400 V	5523603							U2000700
Drainobag® Lock 600 K 10	5523400	40392390000028193A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 600 K 10	5523401							N/A
Drainobag® Lock 600 K 12	5523427							N/A
Drainobag® Lock 600 K 12	5523428							N/A
Intrafix® SafeSet	4063144	40392390000007812U	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4063148							N/A
Intrafix® Primeline	4063287							N/A
ProSet Intrafix® Primeline	4088549							N/A
Intrafix® SafeSet	4110000							N/A
Intrafix® SafeSet	4110010							N/A
ProSet Intrafix® Primeline	4180038							N/A
ProSet Intrafix® SafeSet	4182001A							N/A
ProSet Intrafix® SafeSet	4182002A							N/A
ProSet Intrafix® SafeSet	4182097							N/A
ProSet Intrafix® SafeSet	4182098							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Intrafix® SafeSet	4188137							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	40392390000014832Q	G2S 012974 0457 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® Primeline	4062877		G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Intrafix® SafeSet	4062878							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Intrafix® Primeline	4110001							N/A
Intrafix® Primeline	4110002							N/A
ProSet Intrafix®	4186914							N/A
Intrafix® Primeline	4060563	40392390000014822N	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063000A	40392390000007822W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
SafeSet	4063001CN							N/A
SafeSet	4063003CN							N/A
SafeSet	4063004CN							N/A
SafeSet	4063004SFCN							N/A
SafeSet	4063005CN							N/A
SafeSet	4063006CN							N/A
Infusomat® Plus Line	8700340CN	40392390000008622V	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700330CN							N/A
Infusomat® Plus Line SafeSet	8700240-20							N/A
Infusomat® Plus Line SafeSet	8700280							N/A
Infusomat® Plus Line SafeSet	8700300							N/A
Infusomat® Plus Line	8700340							N/A
Infusomat® Plus Line SafeSet	8700250							N/A
Infusomat® Plus Line SafeSet	8700240							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Plus Line SafeSet	8700220							N/A
Infusomat® Plus Line	8700330							N/A
Infusomat® Plus Line	8700320							N/A
ProSet Original Perfusor® Line	4092930	40392390000014802J	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Original Perfusor® Line	4183945							N/A
ProSet Original Perfusor® Line	4183943							N/A
ProSet Original Perfusor® Line	4183941							N/A
ProSet Original Perfusor® Line	4183938							N/A
Original Perfusor® Line	8723017CN							N/A
Original Perfusor® Line	8722919							N/A
Original Perfusor® Line	8723017							N/A
Original Perfusor® Line	8722919-20							N/A
Original Perfusor® Line	8723017-20							N/A
Original Perfusor® Line	8723018							N/A
ProSet Original Perfusor® Line	4183968							N/A
ProSet Original Perfusor® Line	4093000							N/A
ProSet Original Perfusor® Line	4183937							N/A
ProSet Original Perfusor® Line	4183942							N/A
ProSet Original Perfusor® Line	4183947							N/A
ProSet Original Perfusor® Line	4183930							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Original Perfusor® Line	4183933							N/A
ProSet Original Perfusor® Line	4183935							N/A
ProSet Original Perfusor® Line	4183936							N/A
Infusomat® Plus Line	8700350CN	403923900000086533	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700350-20		NB0123					N/A
Infusomat® Plus Line	8700360							N/A
Infusomat® Space Line	8700132SP	40392390000008693B	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					
Infusomat® Space Line	8270074SP	403923900000086635	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	8250908SP		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Infusomat® Plus Line	8700370CN	40392390000008632X	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700400		NB0123					N/A
Infusomat® Plus Line	8700370							N/A
Omnican® fine	9167641WE	4039239000001006ZF	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnican® fine	9167650WE		NB0123					N/A
Omnican® fine	9167684WE							N/A
Omnican® fine	9167820WE							N/A
Omnican® fine	929G12S-03							N/A
Omnican® fine	929G12S-41							N/A
Omnican® fine	929G12S-43							N/A
Omnican® fine	931G04S-03							N/A
Omnican® fine	931G04S-41							N/A
Omnican® fine	931G04S-43							N/A
Omnican® fine	931G04SCN							N/A
Omnican® fine	931G04SCN1							N/A
Omnican® fine	931G06S-03							N/A
Omnican® fine	931G06S-41							N/A
Omnican® fine	931G06S-43							N/A
Omnican® fine	931G06S-AP							N/A
Omnican® fine	931G06SCN							N/A
Omnican® fine	931G06SCN1							N/A
Omnican® fine	931G08S-03							N/A
Omnican® fine	931G08S-41							N/A
Omnican® fine	931G08S-43							N/A
Omnican® fine	931G08S-44							N/A
Omnican® fine	932G04S-03							N/A
Omnican® fine	932G04S-41							N/A
Omnican® fine	932G04S-43							N/A
Omnican® fine	932G04S-AP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnican® fine	932G04SCN							N/A
Omnican® fine	932G04SCN1							N/A
Omnican® fine	932G05SCN							N/A
Omnican® fine	932G05SCN1							N/A
Omnican® fine	932G06S-03							N/A
Omnican® fine	932G06S-41							N/A
Omnican® fine	932G06S-43							N/A
Omnican® fine	932G06SCN							N/A
Omnican® fine	932G06SCN1							N/A
Omnican® fine	932P04							N/A
Omnican® fine	932P05							N/A
Omnican® fine	932P06							N/A
Infusomat® Plus Line SafeSet	8700270	40392390000020742A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line SafeSet	8700260-20							N/A
Infusomat® Plus Line SafeSet	8700260							N/A
Original Perfusor® Line	8722865	40392390000008722Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Infusomat® Plus Line	8700410	40392390000008642Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4182190SP	403923900000086737	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	4180639SP							N/A
ProSet Infusomat® Space Line	4180020SP							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	8250918SP							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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	4188166SP							N/A
ProSet Infusomat® Space Line	4189980SP							N/A
ProSet Infusomat® Space Line	4186524SP							N/A
ProSet Infusomat® Space Line	4189979SP							N/A
ProSet Infusomat® Space Line	4089340SP							N/A
ProSet Infusomat® Space Line	8250905SP							N/A
ProSet Infusomat® Space Line	4183911							N/A
ProSet Infusomat® Space Line	4185489							N/A
ProSet Infusomat® Space Line	4187769SP							N/A
ProSet Infusomat® Space Line	8251284SP							N/A
ProSet Infusomat® Space Line	4185308SP							N/A
ProSet Infusomat® Space Line	8250904SP							N/A
ProSet Infusomat® Space Line	4186486SP							N/A
Infusomat® Space Line	8700095SP							N/A
Infusomat® Space Line	8700110SP							N/A

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	4183901							N/A
ProSet Infusomat® Space Line	4189981SP							N/A
ProSet Infusomat® Space Line	4187377							N/A
ProSet Infusomat® Space Line	4182189SP							N/A
ProSet Infusomat® Space Line	8252659SP							N/A
ProSet Original Perfusor® Line	4185687	40392390000008712W	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet 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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	40392390000014792Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
ProSet Infusomat® Space Line	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
ProSet Infusomat® Space Line	8252671 SP							N/A
Sangofix®	4050192	40392390000027342Z	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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	4039239000000039ZP	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sangofix® Air	4050151							N/A
Sangofix®	4051998							N/A
Sangofix®	4051998H							N/A
Sangofix®	4052005							N/A
Sangofix®	4052005H							N/A
Sangofix®	4052218H							N/A
Sangofix® Air	4080187							N/A
Sangofix®	4100514							N/A
Sangofix®	4117301							N/A
Sangofix®	4117549							N/A
Original Perfusor® Line	8723001	40392390000027242W	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Infuvalve®	4094000N	40392390000008102A	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Combi-Stopper	4495209	40392390000008112C	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Combi-Stopper	4495101R		NB0123					N/A
Safeflow Extension Set	4097154N	40392390000008152L	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Safeflow Extension Set	4097145N		NB0123					N/A
Safeflow Extension Set	4097154							N/A
Safeflow	409110H	40392390000008162N	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Safeflow	409100CN		NB0123					N/A
Safeflow	409101H							N/A
Safeflow	409100H							N/A
Safeflow Extension Set	4097148N	403923900000027222S	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
			NB0123					

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Omnican® 50	9151117S	40392390000009362Z	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
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	403923900000093937	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
IBSA FSH/LH	9161530S							N/A
Serofine™ needle	16441MS	4039239000001007ZH	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Serofine™ needle	16443MS							N/A
Serofine® needle	16441EMD							N/A
B. Braun Pen Needle	16441CA							N/A
Pencylcap™	P1400060							N/A
Pencylcap™	P1400061							N/A
B. Braun Pen Needle	P1400062							N/A
Pencylcap™	U1244000							N/A
Pencylcap®	U1244100							N/A
B. Braun Pen Needle	P1400062CA							N/A
B. Braun Pen needle	U1244100CA							N/A
Pen Needle B. Braun F-Pen DS	P1400075							N/A
Serofine® needle	16443EMD							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Drainobag® Lock 600 K 14	5523443	40392390000028193A	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Drainobag® Lock 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	4039239000001217ZW	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 100 Duo	9161376C							N/A
Omnifix® 100 Duo	9161376V							N/A
Omnifix® Luer Duo	4643011C	403923900000077633	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® 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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000077735	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Luer Lock Solo	4617022V-03							N/A
Omnifix® Luer Lock Solo	4617029V							N/A
Omnifix® Luer Lock Solo	4617053V							N/A
Omnifix® Luer Lock Solo	4617053V-03							N/A
Omnifix® Luer Lock Solo	4617100CA							N/A
Omnifix® Luer Lock Solo	4617100V							N/A
Omnifix® Luer Lock Solo	4617100V-03							N/A
Omnifix® Luer Lock Solo	4617207V							N/A
Omnifix® Luer Lock Solo	4617207V-03							N/A
Omnifix® Luer Lock Solo	4617304F							N/A
Omnifix® Luer Lock Solo	4617509F							N/A
Omnifix® Luer Lock Solo	4617509F-03							N/A
Omnifix® Luer Lock Solo	4617510F-06	4039239000000207022	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670002S-01	403923900000076936	G1 012974 0607	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Sterican® Safety Needle	4670005S-01		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000076834	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican®	4650034							N/A
Sterican®	4657500							N/A
Sterican®	4657519							N/A
Sterican®	4657527							N/A
Sterican®	4657543							N/A
Sterican®	4657624							N/A
Sterican®	4657640							N/A
Sterican®	4657667							N/A
Sterican®	4657675							N/A
Sterican®	4657683							N/A
Sterican®	4657705							N/A
Sterican®	4657799							N/A
Sterican®	4657853							N/A
Sterican®	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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Sterican®	4665643							N/A
Sterican®	4665791							N/A
Sterican®	4667093							N/A
Sterican®	4667123							N/A
Sterican®	9180109							N/A
Sterican®	9180117							N/A
Sterican®	9186158							N/A
Sterican®	9186166							N/A
Sterican®	9186174							N/A
Sterican®	9186182							N/A
Injekt®-H Luer Duo	9166297	40392390000007742X	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022C	40392390000007752Z	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Injekt® Luer Duo	4645022UA							N/A
Injekt® Luer Duo	4645022V							N/A
Injekt® Luer Duo	4645057C							N/A
Injekt® Luer Duo	4645057UA							N/A
Injekt® Luer Duo	4645057V							N/A
Injekt® Luer Duo	4645065C							N/A
Injekt® Luer Duo	4645103C							N/A
Injekt® Luer Duo	4645103UA							N/A
Injekt® Luer Duo	4645103V							N/A
Injekt® Luer Duo	4645200C							N/A
Injekt® Luer Duo	4645200UA							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Injekt® Luer Duo	4645200V							N/A
Injekt® Luer Duo	4647220							N/A
Injekt®-F Luer Duo	9166033V							N/A
Sterican® Safety Needle	4670030SBR	403923900000076936	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Sterican® Safety Needle	4670053SBR		NB0123					N/A
Contiplex® D	4898323	40392390000008522S	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898325							N/A
Contiplex® D	4898305							N/A
Contiplex® D	4898308							N/A
Contiplex® D	4898311							N/A
Contiplex® D	4898335							N/A
Contiplex® D NRFit®	4898305NR							N/A
Contiplex® D NRFit®	4898335NR							N/A
Contiplex® D NRFit®	4898311NR							N/A
Contiplex® D NRFit®	4898323NR							N/A
Contiplex® D NRFit®	4898325NR							N/A
Contiplex® D	4895819NCN							N/A
Contiplex® D	4894235NCN							N/A
Contiplex® D	4894391NCN							N/A
Contiplex® D	4898205	40392390000008532U	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Contiplex® D	4898211							N/A
Contiplex® D	4898235							N/A
Contiplex® C	4898115	403923900000085000	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Contiplex® C	4898130		NB0123					N/A
Contiplex® C NRFit®	4898115NR							N/A
Contiplex® C NRFit®	4898130NR							N/A
Ultraplex® 360	4892603-01	40392390000008552Y	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Ultraplex® 360	4892603CN							N/A
Ultraplex® 360 NRFit®	4892603NR-01							N/A
Ultraplex® 360	4892605-01							N/A
Ultraplex® 360	4892605CN							N/A
Ultraplex® 360 NRFit®	4892605NR-01							N/A
Ultraplex® 360	4892608-01							N/A
Ultraplex® 360	4892608CN							N/A
Ultraplex® 360 NRFit®	4892608NR-01							N/A
Ultraplex® 360	4892610-01							N/A
Ultraplex® 360	4892610CN							N/A
Ultraplex® 360 NRFit®	4892610NR-01							N/A
Ultraplex® 360	4892615-01							N/A
Ultraplex® 360	4892615CN							N/A
Ultraplex® 360 NRFit®	4892615NR-01							N/A
Stimuplex® D	4892105	40392390000008502N	G1 012974 0607 NB0123	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Stimuplex® D	4892105-23							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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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
Stimuplex® D	4892208							N/A
Stimuplex® D	4892208-23							N/A
Stimuplex® D NRFit®	4892208NR							N/A
Stimuplex® Ultra 360®	4892503-01	40392390000008512Q	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Stimuplex® Ultra 360®	4892503-03		NB0123					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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
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	403923900000044ZG	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Omnifix® Lock	4617014		NB0123					N/A
Omnifix® Lock	4617021							N/A
Omnifix® Lock	4617508F-01							N/A
Original Perfusor® Syringe 20 ml	8728615	403923900000077939	G1 012974 0607	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728615C		NB0123					N/A
Original Perfusor® Syringe 20 ml	8728623	40392390000029923R	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 20 ml	8728623C		NB0123					N/A
Original Perfusor® Syringe 50 ml	8728810F-04							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Original Perfusor® Syringe 50 ml	8728810F-06							8728810F
Original Perfusor® Syringe 50 ml	8728810F-20							N/A
Original Perfusor® Syringe 50 ml	8728844F-04							N/A
Original Perfusor® Syringe 50 ml	8728844F-06	403923900000077939	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	8728844F
Original Perfusor® Syringe 50 ml	8728844F-20							N/A
Original Perfusor® Syringe 50 ml	8728852F-04							N/A
Original Perfusor® Syringe 50 ml	8728852F-06	40392390000029923R	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728852F-20							N/A
Original Perfusor® Syringe 50 ml	8728861F-04							N/A
Original Perfusor® Syringe 50 ml	8728861F-06	403923900000207124	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Original Perfusor® Syringe 50 ml	8728861F-20							N/A
Original Perfusor® Syringe 50 ml	8728845F-01							N/A
Original Perfusor® Syringe 50 ml	8728845F-01	40392390000007802S	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450100	40392390000009993R	G1 012974 0607 NB0123	2024-05-26	TUV SÜD Product Service GmbH (NB0123)	TUV SÜD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450120							N/A
Cystofix®	4450130							N/A

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Cystofix®	4450150							N/A
Cystofix®	4450160							N/A
Cystofix®	4450170							N/A
Cystofix®	4450180							N/A
Cystofix®	4450200	4039239000001000Z3	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix®	4450220		NB0123					N/A
Cystofix SG	4450410	4039239000001002Z7	G1 022239 0080	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix SG	4450412		NB0123 B.BRAUN MEDICAL SAS					N/A
Cystofix SG	4450414							N/A
Cystofix SG	4450416							N/A
Cystofix	4450010	4039239000001001Z5	G1 022239 0080	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Cystofix	4450012		NB0123 B.BRAUN MEDICAL SAS		TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)		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	40392390000009272Y	G1 012974 0607	2024-05-26	TUV SUD Product Service GmbH (NB0123)	TUV SUD Product Service GmbH (NB0123)	2028-12-31	N/A
Vasco® OP Powdered	6031525		NB0123					N/A
Vasco® OP Powdered	6031532							N/A

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

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

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Article name	Article Number (under MDR application)	Basic UDI-DI (under MDR application)						
Vasco® OP Free	9208364							N/A
Drainobag® Connection Tube Bayonet	5524913	40392390000008052H	G1 012974 0607 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	U2170701
Filter Needle	415040	4039239000000290000	G2S 012974 0457 NB0123	2024-05-26	TÜV SÜD Product Service GmbH (NB0123)	TÜV SÜD Product Service GmbH (NB0123)	2028-12-31	4550404
Filter Hub	418021							4551001
Filter Straw	415020							4550200
Filter Straw	415021							4550250
Sterifix® Filter Straw 4"	339171							4550200N
Sterifix® Filter Straw 1.75"	339170							4550250N
Sterifix® Filter Needle 1.5"	339169							4550404N

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Document History

Version	Description of Change
1.0	Initial version

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Title: BBWAG_LM_confirmation letter_Regulation EU 2023/607_G10

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

UserName: Voelske, Rebecca (voelrede)
Title: Head of RA Product Mgmt. Inf. Therapy
Date: Wednesday, 15 May 2024, 15:10 W. Europe Daylight Time
Meaning: Document signed as Author

=====

UserName: Buenger, Joachim (buenjode)
Title: Director Template & Submission Mgmt
Date: Wednesday, 15 May 2024, 15:24 W. Europe Daylight Time
Meaning: Approve Document

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UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 15 May 2024, 16:49 W. Europe Daylight Time
Meaning: Approve Document

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UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 15 May 2024, 17:22 W. Europe Daylight Time
Meaning: Approve Document

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UserName: Arico, Mareike (sommrde)
Title: HC-QM - Head of QM active MD/ Head of Regulatory Affairs CoE AIS
Date: Wednesday, 15 May 2024, 21:34 W. Europe Daylight Time
Meaning: Approve Document

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Title: BBMAG_LM_confirmation letter_Regulation EU 2023/607_G10 Initiator: Anja Mai

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

UserName: Loh, Malte (lohmatde)
Title: HC-RA-DE08 Senior Manager Regulatory Affairs
Date: Thursday, 16 May 2024, 07:36 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Ritz, Frank (ritzfrde)
Title: HC-QM DE08 Head QM CoE Pharmaceuticals
Date: Thursday, 16 May 2024, 08:19 W. Europe Daylight Time
Meaning: Approve Document

=====

UserName: Meyer, Frank (meyefrde)
Title: HC-QM-DE08 Vice President QM Applications Hospital Care
Date: Thursday, 16 May 2024, 09:09 W. Europe Daylight Time
Meaning: Final Release of the Document

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