

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

Kundenspezifische Sets
(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung
1994-12

Gültig bis
2024-05-26

hereby declare in our own responsibility
that the product/s

Customized Kits
(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
amended by Directive 2007/47/EC

Conformity Assessment Procedure
according to annex II (excluding section 4)
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
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Date of first CE-marking
1994-12

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
4087453SP	ProSet Infusions-Set / TYP Space	Ila
4087790SP	ProSet Infusomat® Space Line	Ila
4089340SP	ProSet Infusions-Set / Typ Space	Ila
4089391SP	ProSet Infusomat®Space Line	Ila
4089405SP	ProSet Discofix®C-Hahnbank-Set 3-fach	Ila
4180022SP	ProSet Discofix®C-Hahnbank Set 5-fach	Ila
4180631SP	ProSet Infusomat® Space Line	Ila
4180633SP	ProSet Discofix®C Hahnbank Set 5-fach	Ila
4180635SP	ProSet Discofix®C Hahnbank-Set 3-fach	Ila
4180639SP	ProSet Discofix®C-Hahnbank-Set 3-fach	Ila
4181557SP	ProSet Infusomat® Space Leitung für Transfusion.	Ila
4181558SP	ProSet Infusomat® Space Line	Ila
4182189SP	ProSet Discofix®C-Hahnbank-Set 3-fach	Ila
4182191SP	ProSet Infusomat® Space Line	Ila
4182192SP	PROSET WCS Infusomat® Space Line	Ila
4182193SP	ProSet Infusomat® Space Line	Ila
4182194SP	ProSet Infusomat® Space Line	Ila
4182195SP	ProSet Infusomat® Space Line	Ila
4182196SP	PROSET WCS Infusomat® Space Line	Ila
4182197SP	ProSet Infusomat® Space Line	Ila
4182198SP	ProSet Infusomat® Space Line	Ila
4182199SP	ProSet Infusomat® Space Line	Ila
4182586SP	ProSet Infusomat® Space Line Neutrapur	Ila
4182653SP	ProSet Infusomat® Space Line	Ila
4182654SP	ProSet Infusomat® Space Line	Ila
4182655SP	ProSet Infusomat® Space Line	Ila
4182656SP	ProSet Infusomat® Space Line	Ila
4182657SP	ProSet Infusomat® Space Line	Ila
4182658SP	ProSet Infusomat® Space Line	Ila
4182659SP	ProSet Infusomat® Space Line	Ila
4182660SP	ProSet Infusomat® Space Line	Ila
4182661SP	ProSet Infusomat® Space Line	Ila
4182662SP	ProSet Infusomat® Space Line	Ila
4182663SP	ProSet Infusomat® Space Line	Ila
4183189SP	ProSet Infusomat® Space Line - Neutrapur	Ila
4183878SP	ProSet Discofix®C Hahnbank Set 5-fach	Ila
4183900	ProSet Infusomat® Space Line TYP Airstop	Ila
4183901	ProSet Infusomat® Space Line TYP Airstop	Ila
4183910	ProSet Infusomat®Space Line TYP Airstop	Ila

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
4183911	ProSet Infusomat® Space Line TYP Airstop	Ila
4183918	ProSet Infusomat® Space Leitung TYP Airstop	Ila
4183950SP	ProSet Infusomat® Space Line w. Filter	Ila
4183951SP	ProSet Infusomat® Space Line	Ila
4183952SP	ProSet Infusomat® Space Line	Ila
4183953SP	ProSet Infusomat® Space Line	Ila
4183954SP	ProSet Infusomat® Space Line	Ila
4183955SP	ProSet Infusomat® Space Line	Ila
4183956SP	ProSet Infusomat® Space Line	Ila
4183957SP	ProSet Infusomat® Space Line	Ila
4183958SP	ProSet Infusomat® Space Line	Ila
4183959SP	ProSet Infusomat® Space Line	Ila
4183960SP	ProSet Infusomat® Space Line	Ila
4183961SP	ProSet Infusomat® Space Line	Ila
4184904SP	ProSet Infusomat®-Space Line Typ Airstop	Ila
4185308SP	ProSet Infusions-Set	Ila
4185471SP	ProSet Infusions-Set / TYP Space	Ila
4185489	ProSet Discofix®C-Hahnbank Set 5-fach	Ila
4185976SP	ProSet Infusomat® Space Line	Ila
4186486SP	ProSet Discofix®C Hahnbank-Set 5-fach bunt	Ila
4186524SP	ProSet Infusomat® Space Line	Ila
4186842SP	ProSet Infusomat® Space Line	Ila
4186850	ProSet Infusomat® Space Line	Ila
4186940SP	ProSet Discofix®C -Hahnbank Set 3-fach	Ila
4187105	ProSet Infusions-Set	Ila
4187377	ProSe Discofix®C Hahnbank-Set 3-fach	Ila
4187393SP	ProSet Discofix®C-Hahnbank-Set 5-fach	Ila
4187769SP	ProSet Infusomat® Space Line	Ila
4187789SP	ProSet Infusomat® Space Line	Ila
4187897	ProSet Discofix®C Hahnbank Set 5 fach blau	Ila
4187899	ProSet Discofix®C Hahnbank Set 3 fach bunt	Ila
4187920SP	ProSet Discofix®C-Hahnbank-Set 5-fach	Ila
4188063SP	ProSet Infusomat®-Space Line Typ Airstop	Ila
4188166SP	ProSet Discofix®C-Hahnbank-Set 5-fach	Ila
4189978SP	ProSet Infusomat® Space Line	Ila
4189979SP	ProSet Infusomat® Space Line	Ila
4189980SP	ProSet Infusomat® Space Line	Ila
4189981SP	ProSet Infusomat® Space Line - Neutrapur	Ila
8250077SP	ProSet Infusomat® Space Line - Neutrapur	Ila
8250358SP	ProSet Infusomat® Space Line	Ila
8250900SP	ProSet Infusomat® Space Line	Ila
8250902SP	ProSet Infusomat® Space Line - Neutrapur	Ila

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
8250903SP	ProSet Infusomat® Space Line	Ila
8250904SP	ProSet Infusomat® Space Line - Neutrapur	Ila
8250905SP	ProSet Infusomat® Space Line - Neutrapur	Ila
8250907SP	ProSet Infusomat® Space Line	Ila
8250908SP	ProSet Infusomat® Space Line	Ila
8250909SP	PROSET WCS Infusomat® Space Line - PVC	Ila
8250914SP	PROSET WCS Infusomat® Space Line - PUR	Ila
8250918SP	ProSet Infusomat® Space Line	Ila
8250919SP	ProSet Infusomat® Space Line	Ila
8250921SP	ProSet Infusomat® Space Line	Ila
8250923SP	ProSet Infusomat® Space Line	Ila
8250924SP	ProSet Infusomat® Space Line	Ila
8250925SP	ProSet Infusomat® Space Line	Ila
8250926SP	ProSet Infusomat® Space Line	Ila
8250927SP	ProSet Infusomat® Space Line	Ila
8250928SP	ProSet Infusomat® Space Line	Ila
8250929SP	ProSet Infusomat® Space Line	Ila
8250930SP	ProSet Infusomat® Space Line	Ila
8250931SP	ProSet Infusomat® Space Line	Ila
8250932SP	ProSet Infusomat® Space Line	Ila
8250933SP	ProSet Infusomat® Space Line	Ila
8250934SP	ProSet Infusomat® Space Line	Ila
8250935SP	ProSet Infusomat® Space Line	Ila
8250936SP	ProSet Infusomat® Space Line	Ila
8250937SP	ProSet Infusomat® Space Line	Ila
8250938SP	ProSet Infusomat® Space Line	Ila
8250939SP	ProSet Infusomat® Space Line	Ila
8250940SP	ProSet Infusomat® Space Line	Ila
8250941SP	ProSet Infusomat® Space Line	Ila
8250942SP	ProSet Infusomat® Space Line	Ila
8250943SP	ProSet Infusomat® Space Line	Ila
8250945SP	ProSet Infusomat® Space Line	Ila
8250946SP	ProSet Infusomat® Space Line	Ila
8250947SP	ProSet Infusomat® Space Line	Ila
8250948SP	ProSet Infusomat® Space Line	Ila
8250949SP	ProSet Infusomat® Space Line	Ila
8250950SP	ProSet Infusomat® Space Line	Ila
8250951SP	ProSet Infusomat® Space Line	Ila
8250952SP	ProSet Infusomat® Space Line	Ila
8250953SP	ProSet Infusomat® Space Line	Ila
8250954SP	ProSet Infusomat® Space Line	Ila
8250956SP	PROSET WCS Infusomat® Space Line - PUR	Ila

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
8250957SP	ProSet Infusomat® Space Line	Ila
8250958SP	ProSet Infusomat® Space Line	Ila
8250959SP	ProSet Infusomat® Space Line	Ila
8250960SP	ProSet Infusomat® Space Line	Ila
8250961SP	ProSet Infusomat® Space Line	Ila
8250962SP	ProSet Infusomat® Space Line	Ila
8250963SP	ProSet Infusomat® Space Line	Ila
8250964SP	ProSet Infusomat® Space Line	Ila
8250965SP	ProSet Infusomat® Space Line	Ila
8250967SP	ProSet Infusomat® Space Line	Ila
8250968SP	ProSet Infusomat® Space Line	Ila
8250969SP	ProSet Infusomat® Space Line	Ila
8250971SP	ProSet Infusomat® Space Line	Ila
8250972SP	ProSet Infusomat® Space Line	Ila
8250973SP	ProSet Infusomat® Space Line	Ila
8250974SP	ProSet Infusomat® Space Line	Ila
8250975SP	ProSet Infusomat® Space Line	Ila
8250976SP	ProSet Infusomat® Space Line	Ila
8250977SP	ProSet Infusomat® Space Line	Ila
8250978SP	ProSet Infusomat® Space Line	Ila
8250979SP	ProSet Infusomat® Space Line	Ila
8250981SP	ProSet Infusomat® Space Line	Ila
8250982SP	ProSet Infusomat® Space Line	Ila
8250983SP	ProSet Infusomat® Space Line	Ila
8250984SP	ProSet Infusomat® Space Line	Ila
8250985SP	ProSet Infusomat® Space Line	Ila
8250986SP	ProSet Infusomat® Space Line	Ila
8250987SP	ProSet Infusomat® Space Line	Ila
8250988SP	ProSet Infusomat® Space Line	Ila
8250989SP	ProSet Infusomat® Space Line	Ila
8250995SP	ProSet Infusomat® Space Line	Ila
8250996SP	ProSet Infusomat® Space Line	Ila
8250997SP	ProSet Infusomat® Space Line	Ila
8250998SP	ProSet Infusomat® Space Line	Ila
8250999SP	ProSet Infusomat® Space Line	Ila
8251000SP	ProSet Infusomat® Space Line	Ila
8251001SP	ProSet Infusomat® Space Line	Ila
8251002SP	ProSet Infusomat® Space Line	Ila
8251003SP	ProSet Infusomat® Space Line	Ila
8251004SP	ProSet Infusomat® Space Line	Ila
8251005SP	ProSet Infusomat® Space Line	Ila
8251284SP	ProSet Infusomat® Space Line SafeSet	Ila

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
8252658SP	ProSet Original-Infusomat®- Leitung / Typ Space	Ila
8252659SP	ProSet Infusomat® Space Line - Neutrapur	Ila
8252660SP	ProSet Infusomat® Space Line	Ila
8252661SP	ProSet Infusomat® Space Line	Ila
8252662SP	ProSet Infusomat® Space Line	Ila
8252663SP	ProSet Infusomat® Space Line	Ila
8252664SP	ProSet Infusomat® Space Line	Ila
8252665SP	ProSet Infusomat® Space Line	Ila
8252666SP	ProSet Infusomat® Space Line	Ila
8252667SP	ProSet Infusomat® Space Line	Ila
8252668SP	ProSet Infusomat® Space Line	Ila
8252669SP	ProSet Infusomat® Space Line	Ila
8252670SP	ProSet Infusomat® Space Line	Ila
8252671SP	ProSet Infusomat® Space Line - Neutrapur	Ila
8270058SP	ProSet Infusomat® Space Line	Ila
8270560	ProSet Infusomat® Plus Line	Ila
8270561	PROSET WCS Infusomat® Plus Line - PVC	Ila
8270563	ProSet Infusomat® plus	Ila
8270564	ProSet Infusomat® plus	Ila
8270565	ProSet Infusomat® plus	Ila
8270566	ProSet Infusomat® plus	Ila
8270567	ProSet Infusomat® plus	Ila
8270568	ProSet Infusomat® plus	Ila
8270569	ProSet Infusomat® plus	Ila
8270571	PROSET WCS Infusomat® Plus Line - PUR	Ila
8270572	ProSet Infusomat® plus	Ila
8270573	ProSet Infusomat® plus	Ila
8270574	ProSet Infusomat® plus	Ila
8270575	ProSet Infusomat® plus	Ila
8270576	ProSet Infusomat® plus	Ila
8270577	ProSet Infusomat® plus	Ila
8270578	ProSet Infusomat® plus	Ila
8270579	ProSet Infusomat® plus	Ila
8270580	ProSet Infusomat® plus	Ila
8270581	ProSet Infusomat® plus	Ila
8270597SP	ProSet Infusomat® Space Line	Ila
8270599	ProSet WCS Infusomat® Plus Line - PUR	Ila
8270601	ProSet Infusomat® Plus Line SafeSet	Ila
8270616	ProSet WCS Infusomat® Plus Line - PVC	Ila
8270633	ProSet WCS Infusomat® Plus Line - PVC	Ila
8270660	Original-Infusomat®-Leitung	Ila
8700285	Infusomat Set	Ila

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
8700290	Infusomat Set	Ila

Amendment Information

Version	Description of changes
31.0	Add art. no. 4182194SP, 4182195SP, 4182654SP, 4182655SP, 4182656SP, 4182663SP, 4182198SP, 4182199SP, 4182659SP, 4182660SP, 4182661SP, 4182662SP, 4182193SP, 4182197SP, 4182657SP, 4182658SP, 8250918SP, 8250919SP, 8250921SP, 8250923SP, 8250924SP, 8250925SP, 8250926SP, 8250927SP, 8250928SP, 8250929SP, 8250930SP, 8250931SP, 8250932SP, 8250933SP, 8250934SP, 8250935SP, 8250936SP, 8250937SP, 8250938SP, 8250939SP, 8250940SP, 8250941SP, 8250942SP, 8250943SP, 8250945SP, 8250946SP, 8250947SP, 8250948SP, 8250949SP, 8250950SP, 8250951SP, 8250952SP, 8250953SP, 8250954SP, 8252660SP, 8252661SP, 8252662SP, 8252663SP, 8252664SP, 8252665SP, 8252666SP, 8252667SP, 8252668SP, 8252669SP, 8252670SP, 8250957SP, 8250958SP, 8250959SP, 8250960SP, 8250961SP, 8250962SP, 8250963SP, 8250964SP, 8250965SP, 8250967SP, 8250968SP, 8250969SP, 8250971SP, 8250972SP, 8250973SP, 8250974SP, 8250975SP, 8250976SP, 8250977SP, 8250978SP, 8250979SP, 8250981SP, 8250982SP, 8250983SP, 8250984SP, 8250985SP, 8250986SP, 8250987SP, 8250988SP, 8250989SP, 8250995SP, 8250996SP, 8250997SP, 8250998SP, 8250999SP, 8251000SP, 4183951SP, 4183952SP, 4183953SP, 4183954SP, 4183955SP, 4183956SP, 4183957SP, 4183958SP, 4183959SP, 4183960SP, 8270563, 8270564, 8270565, 8270566, 8270567, 8270568, 8270569, 8270578, 8270579, 8270572, 8270573, 8270574, 8270575, 8270576, 8270577, 8270580, 8270581, 4182192SP, 4182196SP, 8250914SP, 8250956SP, 8250909SP, 8270561, 8270571
32.0	Delete out of market art. no. 4186579SP, 4187962SP Add art. no. 4183961SP, 8251001SP, 8251002SP, 8251003SP, 8251004SP
33.0	Add art. no. 8270601, 8251005SP Change Product Name of art. no. 8251284SP from "ProSet Infusomat® Space Line/ Neutrapur" to "ProSet Infusomat® Space Line SafeSet" and of art. no. no. 4186524SP from "ProSet Infusions-Set Typ Space/Neutrapur" to "ProSet Infusomat® Space Line" Add art. no. 4180631SP former covered by 39.05.050KIT
34.0	Delete out of market art. no. 8250132SP
35.0	Add art. no. 8270616, 8270633, 8270599

Title: Declaration of Conformity - 39.05.018KIT - Infusomat Lines ProSet Initiator: Caroline ? Herbst

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

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Title: Administrator Regulatory Affairs
Date: Friday, 16 April 2021, 11:08 W. Europe Daylight Time
Meaning: Document signed as Author

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Meaning: Approve Document

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Meaning: Approve Document
