

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

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4092931	ProSet Original Perfusor® Line	Ila
4092932	ProSet Original Perfusor® Line	Ila
4092933	ProSet Original Perfusor® Line	Ila
4092934	ProSet Original Perfusor® Line	Ila
4092935	ProSet Original Perfusor® Line	Ila
4092936	ProSet Original Perfusor® Line	Ila
4092939	ProSet Original Perfusor® Line	Ila
4092940	ProSet Original Perfusor® Line	Ila
4092941	ProSet Original Perfusor® Line	Ila
4092942	ProSet Original Perfusor® Line	Ila
4092943	ProSet Original Perfusor® Line	Ila
4092944	ProSet Original Perfusor® Line	Ila
4092947	ProSet Original Perfusor® Line	Ila
4092948	ProSet Original Perfusor® Line	Ila
4092949	ProSet Original Perfusor® Line	Ila
4092950	ProSet Original Perfusor® Line	Ila
4092951	ProSet Original Perfusor® Line	Ila
4092952	ProSet Original Perfusor® Line	Ila
4092954	ProSet Original Perfusor® Line	Ila
4092955	ProSet Original Perfusor® Line	Ila
4092956	ProSet Original Perfusor® Line	Ila
4092957	ProSet Original Perfusor® Line	Ila
4092958	ProSet Original Perfusor® Line	Ila
4092959	ProSet Original Perfusor® Line	Ila
4092960	ProSet Original Perfusor® Line	Ila
4092962	ProSet Original Perfusor® Line	Ila
4092963	ProSet Original Perfusor® Line	Ila
4092964	ProSet Original Perfusor® Line	Ila
4092965	ProSet Original Perfusor® Line	Ila
4092966	ProSet Original Perfusor® Line	Ila
4092967	ProSet Original Perfusor® Line	Ila
4092968	ProSet Original Perfusor® Line	Ila
4092969	ProSet Original Perfusor® Line	Ila
4092971	ProSet Original Perfusor® Line	Ila
4092972	ProSet Original Perfusor® Line	Ila

4092973	ProSet Original Perfusor® Line	Ila
4092974	ProSet Original Perfusor® Line	Ila
4092975	ProSet Original Perfusor® Line	Ila
4092976	ProSet Original Perfusor® Line	Ila
4092977	ProSet Original Perfusor® Line	Ila
4092978	ProSet Original Perfusor® Line	Ila
4092979	ProSet Original Perfusor® Line	Ila
4092980	ProSet Original Perfusor® Line	Ila
4092981	ProSet Original Perfusor® Line	Ila
4092982	ProSet Original Perfusor® Line	Ila
4092983	ProSet Original Perfusor® Line	Ila
4092984	ProSet Original Perfusor® Line	Ila
4092985	ProSet Original Perfusor® Line	Ila
4092986	ProSet Original Perfusor® Line	Ila
4092987	ProSet Original Perfusor® Line	Ila
4092989	ProSet Original Perfusor® Line	Ila
4092990	ProSet Original Perfusor® Line	Ila
4092991	ProSet Original Perfusor® Line	Ila
4092992	ProSet Original Perfusor® Line	Ila
4092993	ProSet Original Perfusor® Line	Ila
4092994	ProSet Original Perfusor® Line	Ila
4092995	ProSet Original Perfusor® Line	Ila
4092997	ProSet Original Perfusor® Line	Ila
4092998	ProSet Original Perfusor® Line	Ila
4092999	ProSet Original Perfusor® Line	Ila
4093000	ProSet Original Perfusor®-Leitung	Ila
4098725	ProSet Original Perfusor® Line	Ila
4180441	ProSet Original Perfusor® Line	Ila
4180442	ProSet Original Perfusor® Line	Ila
4180443	ProSet Original Perfusor® Line	Ila
4180444	ProSet Original Perfusor® Line	Ila
4183913	ProSet Original Perfusor® Line	Ila
4183925	ProSet Original Perfusor® Line	Ila
4183930	ProSet Original Perfusor® Line	Ila
4183933	ProSet Original Perfusor® Line	Ila
4183935	ProSet Original Perfusor® Line	Ila
4183937	ProSet Original Perfusor® Line	Ila
4183946	PROSET WCS Original Perfusor®-Leitung	Ila
4183947	ProSet Original Perfusor® Line	Ila

4183948	ProSet Original Perfusor® Line	Ila
4183949	ProSet Original Perfusor® Line	Ila
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4183956	ProSet Original Perfusor® Line	Ila
4183957	ProSet Original Perfusor® Line	Ila
4183958	ProSet Original Perfusor® Line	Ila
4183960	ProSet Original Perfusor® Line	Ila
4183961	ProSet Original Perfusor® Line	Ila
4183962	ProSet Original Perfusor® Line	Ila
4183963	ProSet Original Perfusor® Line	Ila
4183964	ProSet Original Perfusor® Line	Ila
4183965	ProSet Original Perfusor® Line	Ila
4183966	ProSet Original Perfusor® Line	Ila
4183968	ProSet Original Perfusor® Line	Ila
4183969	ProSet Original Perfusor® Line	Ila
4183970	ProSet Original Perfusor® Line	Ila
4183971	ProSet Original Perfusor® Line	Ila
4183972	ProSet Original Perfusor® Line	Ila
4183973	ProSet Original Perfusor®-Leitung	Ila
4183974	ProSet Original Perfusor®-Leitung	Ila
4184004	ProSet Original Perfusor® Line	Ila
4184006	ProSet Original Perfusor® Line	Ila
4184007	ProSet Original Perfusor® Line	Ila
4184008	ProSet Original Perfusor® Line	Ila
4184010	ProSet Original Perfusor® Line	Ila
4184011	ProSet Original Perfusor® Line	Ila
4184012	ProSet Original Perfusor® Line	Ila
4184013	ProSet Original Perfusor® Line	Ila
4184014	ProSet Original Perfusor® Line	Ila
4184015	ProSet Original Perfusor® Line	Ila
4184016	ProSet Original Perfusor® Line	Ila
4184018	ProSet Original Perfusor® Line	Ila
4184019	ProSet Original Perfusor® Line	Ila
4184020	ProSet Original Perfusor® Line	Ila

4184021	ProSet Original Perfusor® Line	Ila
4185595	ProSet Original Perfusor® Line	Ila
8250782	ProSet Original Perfusor® Line	Ila
8250803	ProSet Original Perfusor® Line	Ila
8250847	ProSet Original Perfusor® Line	Ila
8252828	ProSet Original Perfusor® Line	Ila
8252929	ProSet Original Perfusor®-Leitung	Ila
8272514	ProSet Original Perfusor® Line	Ila

Amendment Information

Version	Description of changes
5.0	Add art. no. 4185841
6.0	Change Product Name of art. no. 4185595 from "ProSet Original Perfusor®-Leitung" to "ProSet Original Perfusor®-Leitung 300 cm"
7.0	Add art. no. 4183946, 4183948, 4183949, 4183950, 4183951, 4183952, 4183953, 4183954, 4183955, 4183956, 4183957, 4183958, 4183960, 4183961, 4183962, 4183963, 4183964, 4183965, 4183966, 4183968, 4183969, 4183970, 4183971, 4183972, 4092931, 4092932, 4092933, 4092934, 4092935, 4092936, 4092939, 4092940, 4092941, 4092942, 4092943, 4092944, 4092947, 4092948, 4092949, 4092950, 4092951, 4092952, 4092954, 4092955, 4092956, 4092957, 4092958, 4092959, 4092960, 4092962, 4092963, 4092964, 4092965, 4092966, 4092967, 4092968, 4092969, 4092971, 4092972, 4092973, 4092974, 4092975, 4092976, 4092977, 4092978, 4092979, 4092980, 4092981, 4092982, 4092983, 4092984, 4092985, 4092986, 4092987, 4092989, 4092990, 4092991, 4092992, 4092993, 4092994, 4092995, 4092997, 4092998, 4092999, 4184007, 4184008, 4184010, 4184011, 4184012, 4184013, 4184014, 4184015, 4184016, 4184018, 4184019, 4184020, 4184021, 4180441, 4180442, 4180443, 4180444
8.0	Add art. no. 4183974, 4183973, 4093000
9.0	Add art. no. 8252828 formerly covered by 39.05.001KIT Add art. no. 4183947, 4098725, 4183913, 4184006, 4183933, 4183930, 4183935, 4184004, 4183925, 4183937 formerly covered by 39.05.008KIT Delete art. no. 4182097 which will be covered by 39.05.005KIT Harmonize Product Name of art. no. 8250847, 8250803, 8250782, 8272514, 4185595 to "ProSet Original Perfusor® Line" Delete art. no. 4185841 which will be covered by 39.05.013KIT

Title: Declaration of Conformity - 39.05.003KIT - Original Perfusor Line ProSet Initiator: Caroline ? Herbst

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

UserName: Herbst, Caroline (fuehcade)
Title: Administrator Regulatory Affairs
Date: Tuesday, 11 May 2021, 14:56 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Tuesday, 11 May 2021, 18:44 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Seidel, Stefan (seidstde)
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Date: Wednesday, 12 May 2021, 14:29 W. Europe Daylight Time
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