

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

hereby declare in our own responsibility
that the product/s

Kundenspezifische Sets
(Artikelnummern siehe Anlage I)

Customized Kits
(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/EG

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

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

Conformity Assessment Procedure
according to annex II (excluding section 4)
of the Council Directive named above

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa

Classification
according to annex IX of the
Council Directive named above
Class IIa

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

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Datum der ersten CE-Kennzeichnung
1994-12

Date of first CE-marking
1994-12

Gültig bis
2024-05-26

Valid until
2024-05-26

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 |

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| 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 |

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| 4183948 | ProSet Original Perfusor® Line | Ila |
| 4183949 | ProSet Original Perfusor® Line | Ila |
| 4183950 | ProSet Original Perfusor® Line | Ila |
| 4183951 | ProSet Original Perfusor® Line | Ila |
| 4183952 | ProSet Original Perfusor® Line | Ila |
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| 4183955 | ProSet Original Perfusor® Line | Ila |
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| 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 |

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| 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

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

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Wednesday, 12 May 2021, 14:29 W. Europe Daylight Time
Meaning: Approve Document

Effective