

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

**Infusionsleitung PE,
Infusions-Leitung PE,
Original Perfusor®-Leitung,
Original-Perfusor® Leitung PCA,
Original Perfusor®-Leitung Typ: MR,
Original Perfusor®-Leitung Typ: MK,
Original Perfusor® Line,
Original Perfusor® Tubing PE,
Sistema para perfusão/Système de perfusion**

**Infusionsleitung PE,
Infusions-Leitung PE,
Original Perfusor®-Leitung,
Original-Perfusor® Leitung PCA,
Original Perfusor®-Leitung Typ: MR,
Original Perfusor®-Leitung Typ: MK,
Original Perfusor® Line,
Original Perfusor® Tubing PE,
Sistema para perfusão/Système de perfusion**

Verlängerungsleitungen
(Artikelnummern siehe Anlage I)

Extension Fluid Lines
(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

Gültig bis

2024-05-26

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
8724415	Infusionsleitung PE	Ila
8724032	Infusions-Leitung PE	Ila
0009483H	Original Perfusor® Line	Ila
0066086H	Original Perfusor® Line	Ila
0066087J	Original Perfusor® Line	Ila
0066088K	Original Perfusor® Line	Ila
8250146	Original Perfusor® Line	Ila
8255059	Original Perfusor® Line	Ila
8255067	Original Perfusor® Line	Ila
8255172	Original Perfusor® Line	Ila
8255253	Original Perfusor® Line	Ila
8255490	Original Perfusor® Line	Ila
8255504N	Original Perfusor® Line	Ila
8255504NCN	Original Perfusor® Line	Ila
8272565	Original Perfusor® Line	Ila
8722820	Original Perfusor® Line	Ila
8722862	Original Perfusor® Line	Ila
8722862-20	Original Perfusor® Line	Ila
8722865	Original Perfusor® Line	Ila
8722870N	Original Perfusor® Line	Ila
8722919	Original Perfusor® Line	Ila
8722919-20	Original Perfusor® Line	Ila
8722935	Original Perfusor® Line	Ila
8722935-20	Original Perfusor® Line	Ila
8722935CN	Original Perfusor® Line	Ila
8722940	Original Perfusor® Line	Ila
8722941	Original Perfusor® Line	Ila
8722960	Original Perfusor® Line	Ila
8722960-20	Original Perfusor® Line	Ila
8723001	Original Perfusor® Line	Ila
8723010	Original Perfusor® Line	Ila
8723017	Original Perfusor® Line	Ila
8723017-20	Original Perfusor® Line	Ila
8723017CN	Original Perfusor® Line	Ila
8723018	Original Perfusor® Line	Ila
8723020	Original Perfusor® Line	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
8723021	Original Perfusor® Line	Ila
8723023	Original Perfusor® Line	Ila
8723024	Original Perfusor® Line	Ila
8723025	Original Perfusor® Line	Ila
8723026	Original Perfusor® Line	Ila
8723060	Original Perfusor® Line	Ila
8723060-20	Original Perfusor® Line	Ila
8723060CN	Original Perfusor® Line	Ila
8745919N	Original Perfusor® Line	Ila
8750645	Original Perfusor® Line	Ila
8745641	Original Perfusor® Tubing PE	Ila
8722960TR	Original Perfusor®-Leitung	Ila
8722889	Original Perfusor®-Leitung Typ: MK	Ila
8255504	Original Perfusor®-Leitung Typ: MR	Ila
8722870	Original Perfusor®-Leitung Typ: MR	Ila
8745919	Original Perfusor®-Leitung Typ: MR	Ila
8726019	Original-Perfusor® Leitung PCA	Ila
0086789H	Sistema para perfusão/Système de perfusion	Ila
411402	Sistema para perfusão/Système de perfusion	Ila

Amendment Information

Version	Description of the changes
27.0	Add art. no. 8722865
28.0	Add art. no. 8722935CN, 8723060CN, 8723017CN
29.0	Add art. no. 8723020, 8723021, 8723023, 8723024, 8723025, 8723026
30.0	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
31.0	Delete 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 (will be covered by 39.05.003KIT)

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

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