

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

**Double Spike Adaptor,
Extension Line,
LS-2 Mini-Lumen with Safsite®,
LS-2 Connector,
LS-3 Connector,
LS-4 Connector,
LS-5 Connector,
Prolongateur,
Prolongateur Exadrop,
Prolongateur Linéaire,
Prolongateur Robinet**
Leitungsverbinder

**Alargadera,
Verbindungsleitung**
Verbindungsleitung

Verbindungsstück mit Injektionsport
Verbindungsstück

**Heidelberger Extension Tubing,
Extension Line, Type: Heidelberger,
Extension Line**
Verlängerungsleitung

**Minimum Volume Extension Tubing,
Original-Kucher-Verlängerungsstück,
Verlängerungsleitung**
Extension Tubing

(Artikelnummern siehe Anlage I)
mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993

hereby declare in our own responsibility
that the product/s

**Double Spike Adaptor,
Extension Line,
LS-2 Mini-Lumen with Safsite®,
LS-2 Connector,
LS-3 Connector,
LS-4 Connector,
LS-5 Connector,
Prolongateur,
Prolongateur Exadrop,
Prolongateur Linéaire,
Prolongateur Robinet**
Tube Connector

**Alargadera,
Verbindungsleitung**
Connection Tubing

Verbindungsstück mit Injektionsport
Connecting Piece

**Heidelberger Extension Tubing,
Extension Line, Type: Heidelberger,
Extension Line**
Extension Line

**Minimum Volume Extension Tubing,
Original-Kucher-Verlängerungsstück,
Verlängerungsleitung**
Extension Tubing

(article numbers see attachment I)
is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993

über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

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

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa
Klasse I steril

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

Datum der ersten CE-Kennzeichnung

Heidelberger Verlängerungsleitungen	1994-12
Koppelsystem	2000-03
Leitungsverbinder	1994-12
LS-Verbinder	1994-12
Prolongateurs	1997-12
Verbindungsleitungen	1997-09

Gültig bis
2024-05-26

concerning Medical Devices
amended by Directive 2007/47/EC

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

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

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

Date of first CE-marking

Heidelberger Extension Tubings	1994-12
Koppelsystem	2000-03
Tube Connectors	1994-12
LS-Connectors	1994-12
Prolongateurs	1997-12
Connection Tubings	1997-09

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
0086659S	Prolongateur Linéaire	Ila
0086660T	Prolongateur Linéaire	Ila
0086662V	Prolongateur Linéaire	Ila
0086663W	Prolongateur Linéaire	Ila
0086666Z	Prolongateur	Ila
0086669C	Prolongateur Exadrop	Ila
0086671E	Prolongateur Robinet	Ila
0086674H	Prolongateur Robinet	Ila
4033019	Heidelberger Extension Tubing	Ila
4033809	Heidelberger Extension Tubing	Ila
4034589	Heidelberger Extension Tubing	Ila
4038703	Heidelberger Extension Tubing	Ila
4039386	Minimum Volume Extension Tubing	Ila
4051807	Extension Line	Ila
4052145	Heidelberger Extension Tubing	Ila
4052197	Heidelberger Extension Tubing	Ila
4052197H	Heidelberger Extension Tubing	Ila
4053753	LS-3 Connector	Ila
4054032	Double Spike Adaptor	Ila
4054393	Extension Line	Ila
4054394	Extension Line	Ila
4055128	Heidelberger Extension Tubing	Ila
4055136	Heidelberger Extension Tubing	Ila
4055137	Extension Line	Ila
4055138	Extension Line	Ila
4055139	Extension Line	Ila
4055140	Extension Line	Ila
4055141	Extension Line	Ila
4055145	Extension Line	Ila
4055146	Extension Line	Ila
4055147	Extension Line	Ila
4055148	Extension Line	Ila
4055149	Extension Line	Ila
4055150	Extension Line	Ila
4091043	LS-2 Mini-Lumen mit Safsite®	Ila
4094603	Alargadera	Ila
4097122	LS-2 Connector	Ila
4097130	Extension Line, Type: Heidelberger	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4097149	LS-4 Connector	Ila
4097157	LS-5 Connector	Ila
4097173	Extension Line, Type: Heidelberger	Ila
4097190	Extension Line, Type: Heidelberger	Ila
4097262	Extension Line, Type: Heidelberger	Ila
4097290	Extension Line, Type: Heidelberger	Ila
4097291	Extension Line, Type: Heidelberger	Ila
4097300	Extension Line, Type: Heidelberger	Ila
4097408	Extension Line, Type: Heidelberger	Ila
4097572	Extension Line	Ila
4247116	Connecting piece with injection port	Ila
4256000	Verlängerungsleitung	Ila
4256034	Verlängerungsleitung	Ila
4256166	Verbindungsleitung	Ila
4887441	Original-Kucher-Verlängerungsstück	Ila
9500049	Extension Line	Ila
9500057	Extension Line	Ila
9500065	Extension Line	Ila
9500103	LS-2 Connector	Ila

Amendment Information

Version	Description of changes
31.0	Add art. no. 4055137, 4055138, 4055139, 4055140, 4055141, 4055150, 4055145, 4055146, 4055147, 4055148 Delete Out of Market art. no. 4050136, 0045593H
32.0	Delete Out of Market art. no. 4092210
33.0	Delete Out of Market art. no. 0083426F Delete art. no. 4090365, 4090373, 4092937, 4092945 will be covered by DoC 39.05.013KIT
34.0	Add art. no. 4055149
35.0	Delete Out of Market art. no. 0086787F, 4052625, 0086786E, 0086672F, 0086670D, 0086673G

Title: Declaration of Conformity - 39.05.013 - Extension Lines 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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