

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)
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
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)
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
1994-12

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4090144	ProSet Verbindungsleitung	Ila
4090365	Spiral Line	Ila
4090373	Spiral Line	Ila
4090381	ProSet Spiral Line	Ila
4090383	ProSet Spiral line yellow	Ila
4090390	ProSet Spiral Line	Ila
4090438	ProSet Spiral Line	Ila
4091051	ProSet Verbindungsleitung	Ila
4091620	ProSet Verbindungsleitung	Ila
4091621	ProSet 2-Lumen Verbindungsleitung gelb/transp	Ila
4091622	ProSet 3-Lumen Verbindungsleitung transp/gelb/blau	Ila
4091623	PROSET WCS Verbindungsleitung	Ila
4091624	ProSet Extension Line	Ila
4091625	ProSet Extension Line	Ila
4091626	ProSet Extension Line	Ila
4091627	ProSet Extension Line	Ila
4091628	ProSet Extension Line	Ila
4091629	ProSet Extension Line	Ila
4091630	ProSet Verbindungsleitung	Ila
4091631	ProSet Extension Line	Ila
4091632	ProSet Extension Line	Ila
4091633	ProSet Extension Line	Ila
4091634	ProSet Extension Line	Ila
4091635	ProSet Extension Line	Ila
4091636	ProSet Extension Line	Ila
4091637	ProSet Extension Line	Ila
4091638	ProSet Extension Line	Ila
4091640	ProSet Extension Line	Ila
4091641	ProSet Extension Line	Ila
4091642	ProSet Extension Line	Ila
4091643	ProSet Extension Line	Ila
4091644	ProSet Extension Line	Ila
4091645	ProSet Extension Line	Ila
4091646	ProSet Extension Line	Ila
4091647	ProSet LS-2 Verbinder mini	Ila
4091648	ProSet Extension Line	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4091649	ProSet Extension Line	Ila
4091650	ProSet Extension Line	Ila
4091651	ProSet Extension Line	Ila
4091652	ProSet Extension Line	Ila
4091653	ProSet Extension Line	Ila
4091654	ProSet Extension Line	Ila
4091656	ProSet Extension Line	Ila
4091657	ProSet Extension Line	Ila
4091658	ProSet Extension Line	Ila
4091659	ProSet Extension Line	Ila
4091660	ProSet Extension Line	Ila
4091661	ProSet Extension Line	Ila
4091662	ProSet Extension Line	Ila
4091664	ProSet Extension Line	Ila
4091665	ProSet Extension Line	Ila
4091666	ProSet Extension Line	Ila
4091667	ProSet Extension Line	Ila
4091668	ProSet Extension Line	Ila
4091669	ProSet Extension Line	Ila
4091670	ProSet Extension Line	Ila
4091672	ProSet Extension Line	Ila
4091673	ProSet Extension Line	Ila
4091674	ProSet Extension Line	Ila
4091675	ProSet Extension Line	Ila
4091728	ProSet Doppellumen-Spiralleitung	Ila
4091736	ProSet Doppellumen-Spiralleitung	Ila
4091740	ProSet Doppellumen-Spiralleitung	Ila
4091752	ProSet Doppellumen-Spiralleitung	Ila
4091884	ProSet Doppellumen-Spiralleitung	Ila
4092539	ProSet Spiral Line	Ila
4092929	ProSet Verbindungsleitung	Ila
4092930	ProSet Verbindungsleitung	Ila
4092937	Spiral Line	Ila
4092945	Spiral Line	Ila
4092946	ProSet Spiral Line	Ila
4092953	ProSet Spiral line PUR	Ila
4092961	ProSet Spiral line PUR	Ila
4092970	ProSet Spiral Line	Ila
4093038	ProSet LS-2 Connector	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4093054	ProSet Extension Line	Ila
4093070	ProSet Verbindungsleitung PUR	Ila
4093115	ProSet Triplelumen-Spiralleitung	Ila
4093130	ProSet Triplelumen-Spiralleitung	Ila
4093150	ProSet Triplelumen-Spiralleitung	Ila
4093170	ProSet Triplelumen-Spiralleitung	Ila
4093185	ProSet Triplelumen-Spiralleitung	Ila
4093215	ProSet Triplelumen-Spiralleitung	Ila
4093224	ProSet LS-2 Verbinder	Ila
4093230	ProSet Triplelumen-Spiralleitung	Ila
4093250	ProSet Triplelumen-Spiralleitung	Ila
4093270	ProSet Triplelumen-Spiralleitung	Ila
4093285	ProSet Triplelumen-Spiralleitung	Ila
4093402	ProSet Verlängerungsleitung	Ila
4093437	ProSet Verlängerungsleitung	Ila
4093438	ProSet Verbindungsleitung PUR	Ila
4093534	ProSet Spiralleitung PE	Ila
4093550	ProSet Verbindungsleitung –TIVA-	Ila
4093577	ProSet Verbindungsleitung	Ila
4093585	ProSet Doppellumen-Spiralleitung	Ila
4093607	ProSet Doppellumen-Spiralleitung	Ila
4093623	ProSet Verbindungsleitung	Ila
4093830	Doppellumen-Spiralleitung	Ila
4093850	Doppellumen-Spiralleitung	Ila
4093870	Doppellumen-Spiralleitung	Ila
4093885	Doppellumen-Spiralleitung	Ila
4095251	ProSet Extension Line Type: Heidelberger	Ila
4095260	ProSet Verbindungsleitung	Ila
4097050	ProSet Heidelberger Verlängerung	Ila
4097150	ProSet LS-4 Verbinder	Ila
4097151	ProSet LS-3 Verbinder	Ila
4097531	ProSet Verbindungsleitung-PUR	Ila
4099362	ProSet Doppellumen-Spiralleitung	Ila
4099363	PROSET WCS SPIRALLEITUNG	Ila
4099364	ProSet Spiral Line	Ila
4099365	ProSet Spiral Line	Ila
4099366	ProSet Spiral Line	Ila
4099367	ProSet Spiral Line	Ila
4099368	ProSet Spiral Line	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4099369	ProSet Spiral Line	IIa
4099370	ProSet Spiral Line	IIa
4099371	ProSet Spiral Line	IIa
4099372	ProSet Spiral Line	IIa
4099373	ProSet Spiral Line	IIa
4099374	ProSet Spiral Line	IIa
4099375	ProSet Spiral Line	IIa
4099376	ProSet Spiral Line	IIa
4099377	ProSet Spiral Line	IIa
4099378	ProSet Spiral Line	IIa
4099379	ProSet Spiral Line	IIa
4099380	ProSet Spiral Line	IIa
4099381	ProSet Spiral Line	IIa
4099382	ProSet Spiral Line	IIa
4099383	ProSet Spiral Line	IIa
4099384	ProSet Spiral Line	IIa
4099385	ProSet Spiral Line	IIa
4099386	ProSet Spiral Line	IIa
4099387	ProSet Spiral Line	IIa
4099388	ProSet Spiral Line	IIa
4099389	ProSet Spiral Line	IIa
4099390	ProSet WCS SPIRALLEITUNG	IIa
4099391	ProSet Spiral Line	IIa
4099392	ProSet Spiral Line	IIa
4099393	ProSet Spiral Line	IIa
4099394	ProSet Spiral Line	IIa
4099395	ProSet Spiral Line	IIa
4099396	ProSet Spiral Line	IIa
4099397	ProSet Spiral Line	IIa
4099398	ProSet Spiral Line	IIa
4099399	ProSet Spiral Line	IIa
4099401	ProSet Spiral Line	IIa
4099402	ProSet Spiral Line	IIa
4099403	ProSet Spiral Line	IIa
4099404	ProSet Spiral Line	IIa
4099405	ProSet Spiral Line	IIa
4181234	ProSet Discofix® Hahnbank Set 5-fach	IIa
4181289	ProSet Discofix®Hahnbank Set 3-fach	IIa
4182180	ProSet Verlängerungsleitung	IIa

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4182555	ProSet LS-3 Verbinder	Ila
4182562	ProSet LS-4 Connector	Ila
4182581	ProSet LS-2 Connector	Ila
4185744	ProSet Ernährungs-Set Pädiatrie	Ila
4185745	ProSet Ernährungs-Set Pädiatrie	Ila
4185838	ProSet Verbindungsleitung	Ila
4185841	ProSet Verbindungsleitung	Ila
4185842	ProSet Verbindungsleitung 10 Stück/Set	Ila
4185843	PROSET WCS Verbindungsleitung	Ila
4185844	PROSET WCS Verbindungsleitung	Ila
4185845	ProSet Extension Line	Ila
4185847	ProSet Extension Line	Ila
4185848	ProSet Extension Line	Ila
4185849	ProSet Extension Line	Ila
4185850	ProSet Extension Line	Ila
4185851	ProSet Extension Line	Ila
4185852	ProSet Extension Line	Ila
4185853	ProSet Extension Line	Ila
4185855	ProSet Extension Line	Ila
4185856	ProSet Extension Line	Ila
4185857	ProSet Extension Line	Ila
4185858	ProSet Extension Line	Ila
4185859	ProSet Extension Line	Ila
4185860	ProSet Extension Line	Ila
4185861	ProSet Extension Line	Ila
4185863	ProSet Extension Line	Ila
4185864	ProSet Extension Line	Ila
4185865	ProSet Extension Line	Ila
4185866	ProSet Extension Line	Ila
4185867	ProSet Extension Line	Ila
4185868	ProSet Extension Line	Ila
4185869	ProSet Extension Line	Ila
4185871	ProSet Extension Line	Ila
4185872	ProSet Extension Line	Ila
4185873	ProSet Extension Line	Ila
4185874	ProSet Extension Line	Ila
4185876	ProSet Extension Line	Ila
4185877	ProSet Extension Line	Ila
4185878	ProSet Extension Line	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4185879	ProSet Extension Line	Ila
4185880	ProSet Extension Line	Ila
4185881	ProSet Extension Line	Ila
4185882	ProSet Extension Line	Ila
4185883	ProSet Extension Line	Ila
4185884	ProSet Extension Line	Ila
4186010	ProSet Infusions-Set	Ila
4186630	ProSet Infusions-Set	Ila
4187466	ProSet Doppellumen-Spiralleitung-Set	Ila
4187467	ProSet Dreilumen-Spiralleitung Set	Ila
4187470	ProSet Spiral Line	Ila
4187471	ProSet Spiral Line	Ila
4187472	ProSet Spiral Line	Ila
4187473	ProSet Spiral Line	Ila
4187475	ProSet Spiral Line	Ila
4187476	ProSet Spiral Line	Ila
4187477	ProSet Spiral Line	Ila
4187478	ProSet Spiral Line	Ila
4187479	ProSet Spiral Line	Ila
4187480	ProSet Spiral Line	Ila

Amendment Information

Version	Description of changes
38.0	Add art. no. 4182581
39.0	Delete art. no. 4187172 (will be covered by 39.05.005KIT)
40.0	Change product name of art. no. 4099390 from "ProSet Spiral Line" to "ProSet WCS SPIRALLEITUNG"
41.0	Change product name of art. no. 4093038 from "ProSet Paed. LS-2 Verbinder" to "ProSet LS-2 Connector"
42.0	Add art. no. 4182562 and 4182555 formerly covered by 39.05.008KIT Add art. no. 4185841 formerly covered by 39.05.003KIT

Title: Declaration of Conformity - 39.05.013KIT - Extension Lines 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, 14:52 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, 18:40 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
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Date: Wednesday, 12 May 2021, 14:30 W. Europe Daylight Time
Meaning: Approve Document
