

## 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**  
1998-07

**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 14<sup>th</sup> 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**  
1998-07

**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4094612	ProSet Top line adapter	Ila
4182697	ProSet Cyto-Set Mix Luer Lock	Ila
4182698	ProSet Cyto-Set® Mix LL with 0,2µm Filter	Ila
4182699	ProSet Cyto-Set Mix Luer Lock	Ila
4182700	ProSet Cyto-Set® Mix	Ila
4182701	ProSet Cyto-Set® Mix	Ila
4182702	ProSet Cyto-Set® Mix	Ila
4182703	ProSet Cyto-Set® Mix	Ila
4182704	ProSet Cyto-Set® Pump Adapter	Ila
4182705	ProSet Cyto-Set® Mix	Ila
4182706	ProSet Cyto-Set® Mix	Ila
4182708	ProSet Cyto-Set® Mix	Ila
4182709	ProSet Cyto-Set® Line	Ila
4182710	ProSet Cyto-Set® Line	Ila
4182711	ProSet Cyto-Set® Line	Ila
4182721	ProSet Cyto-Set® Mix mit RV	Ila
4182724	ProSet Cyto-Set Mix	Ila
4182726	ProSet Cyto-Set® Mix	Ila
4182727	ProSet Cyto-Set® Mix	Ila
4182728	ProSet Cyto-Set® Line	Ila
4182729	ProSet Cyto-Set® Mix	Ila
4182729S	ProSet Cyto-Set® Mix with BCV w. Safeflow	Ila
4182730	ProSet Cyto-Set® Mix	Ila
4182734	ProSet Cyto-Set® Line	Ila
4182800	PROSET WCS Cyto-Set® Mix w. Filter PVC	Ila
4182801	PROSET WCS Cyto-Set® Mix w. Filter PUR	Ila
4182802	ProSet Cyto-Set® Mix	Ila
4182803	ProSet Cyto-Set® Mix	Ila
4182805	ProSet Cyto-Set® Mix	Ila
4182806	ProSet Cyto-Set® Mix	Ila
4182807	ProSet Cyto-Set® Mix	Ila
4182808	ProSet Cyto-Set® Mix	Ila
4182809	ProSet Cyto-Set® Mix	Ila
4182810	ProSet Cyto-Set® Mix	Ila
4182811	ProSet Cyto-Set® Mix	Ila
4182816	ProSet Cyto-Set® Mix	Ila
4182817	ProSet Cyto-Set® Mix	Ila
4182818	ProSet Cyto-Set® Mix	Ila
4182819	ProSet Cyto-Set® Mix	Ila
4182821	ProSet Cyto-Set® Mix	Ila
4182822	ProSet Cyto-Set® Mix	Ila
4182823	ProSet Cyto-Set® Mix	Ila
4182824	ProSet Cyto-Set® Mix	Ila

4182825	ProSet Cyto-Set® Mix	Ila
4182826	ProSet Cyto-Set® Mix	Ila
4185714	ProSet Einstechdorn PVC-frei	Ila
4185722	ProSet Ernährungs-Set	Ila
4188090	ProSet Cyto-Set® Mix	Ila
4188091	ProSet Cyto-Set® Mix	Ila
4188092	ProSet Cyto-Set® Mix	Ila
4188093	ProSet Cyto-Set® Line	Ila
4188712	ProSet Infusions-Set	Ila
4188713	ProSet Infusions-Set	Ila
4188714	ProSet Infusions-Set	Ila
4188715	ProSet Infusions-Set	Ila
4188925	ProSet Cyto-Set® Mix	Ila
4188926	ProSet Cyto-Set® Mix	Ila
4188927	ProSet Cyto-Set® Mix w. 0,2µm Filter	Ila
8250144SP	ProSet Cyto-Set® Typ Space mit 3x Safsite®	Ila
8250155SP	ProSet Cyto-Set® Typ Space mit 5x Safsite®	Ila
8250244	ProSet Cyto-Set® mit 3x Safsite	Ila
8250266	ProSet Cyto-Set® mit 3 Ventilen	Ila
8250344	ProSet Cyto-Set® mit 5x Safsite®	Ila
8250366	ProSet Cyto-Set® mit 5 Ventilen	Ila
8250370	ProSet Cyto-Set®	Ila
8250444SP	ProSet Cyto-Set® Typ Space mit 4x Safsite®	Ila
8250455SP	ProSet Cyto-Set® Space Line UV-Protect mit 4 Ventilen	Ila
8250644SP	ProSet Cyto-Set® Typ Space mit 5x Safsite®	Ila
8250650SP	ProSet Cyto-Set® Typ Space mit 5 Ventilen	Ila
8250655SP	ProSet Cyto-Set® Typ Space mit 5 Ventilen	Ila
8250815SP	ProSet Cyto-Set® Typ Space mit 5x Safsite®	Ila
8250818SP	ProSet Cyto-Set® Typ Space mit 5 Ventilen	Ila
8250844SP	ProSet Cyto-Set® Typ Space mit 2x Safsite®	Ila
8250866SP	ProSet Cyto-Set® Typ Space mit 2 Ventilen	Ila
8250912SP	ProSet Cyto-Set® Typ Space mit 3x Safsite®	Ila
8250915SP	ProSet Cyto-Set® Typ Space mit 3 Ventilen	Ila
8250944SP	ProSet Cyto-Set® Typ Space mit 4x Safsite®	Ila
8250966SP	ProSet Cyto-Set® Typ Space mit 4 Ventilen	Ila
8250970SP	ProSet Cyto-Set® Typ Space mit 3 Ventilen	Ila
8250980SP	ProSet Cyto-Set® Typ Space mit 5 Ventilen	Ila
8250990SP	ProSet Cyto-Set® Typ Space	Ila
8250991SP	ProSet Cyto-Set® Typ Space	Ila
8250992SP	ProSet Cyto-Set® Typ Space	Ila
8250993SP	ProSet Cyto-Set® Typ Space	Ila
8250994SP	ProSet Cyto-Set® Typ Space	Ila
8251044SP	ProSet Cyto-Set® Typ Space mit 5x Safsite®	Ila
8251055SP	ProSet Cyto-Set® Typ Space mit 5 Ventilen	Ila
8270300	ProSet Cyto-Set® Infusomat® Plus	Ila
8270582	ProSet Cyto-Set® Infusomat® plus	Ila
8270583	ProSet Cyto-Set® Infusomat® plus	Ila
8270584	ProSet Cyto-Set® Infusomat® plus	Ila

8270585	ProSet Cyto-Set®	Ila
8270586	ProSet Cyto-Set®	Ila
8270587	ProSet Cyto-Set®	Ila
8270588	PROSET WCS CYTO-SET TYP PLUS Line PUR	Ila
8270590	ProSet Cyto-Set® Infusomat® plus	Ila
8270591	ProSet Cyto-Set® Infusomat® plus	Ila
8270592	ProSet Cyto-Set® Infusomat® plus	Ila
8270593	ProSet Cyto-Set® Infusomat® plus	Ila
8270594	PROSET WCS Cyto-Set PVC	Ila
8270595	ProSet Cyto-Set®	Ila
8270596	ProSet Cyto-Set®	Ila
8270598	ProSet Cyto-Set®	Ila
8350866SP	ProSet Cyto-Set® Typ Space mit 2 Ventilen	Ila
8350966SP	ProSet Cyto-Set® Typ Space mit 4 Ventilen	Ila
8351655SP	ProSet Cyto-Set® Typ Space mit 5 Ventilen	Ila
8352055SP	ProSet Cyto-Set® Typ Space mit 9 Ventilen	Ila
8352056SP	PROSET WCS Cyto-Set® Type Space PVC	Ila
8352057SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352058SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352059SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352060SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352061SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352062SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352063SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352064SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352065SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352066SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352067SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352068SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352069SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352070SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352071SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352072SP	PROSET WCS Cyto-Set® Typ Space PUR	Ila
8352073SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352074SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352075SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352076SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352077SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352078SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352079SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352080SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352081SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352082SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352083SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352084SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352085SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352086SP	ProSet Cyto-Set® Infusomat® Space	Ila
8352087SP	ProSet Cyto-Set® Infusomat® Space	Ila

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
40.0	Add art. no. 8250650SP, 4182708, 4182728
41.0	Add art. no. 8270300, 8250370, 8352057SP, 8352058SP, 8352059SP, 8352060SP, 8352061SP, 8352062SP, 8352063SP, 8352064SP, 8352065SP, 8352066SP, 8352067SP, 8352068SP, 8352069SP, 8352070SP, 8352071SP, 8352073SP, 8352074SP, 8352075SP, 8352076SP, 8352077SP, 8352078SP, 8352079SP, 8352080SP, 8352081SP, 8352082SP, 8352083SP, 8352084SP, 8352085SP, 8352086SP, 8352087SP, 8270590, 8270591, 8270592, 8270593, 8270582, 8270583, 8270584, 8270595, 8270596, 8270598, 8270585, 8270586, 8270587, 8352056SP, 8352072SP, 8270588, 8270594, 4182802, 4182803, 4182805, 4182806, 4182807, 4182808, 4182809, 4182810, 4182811, 4182816, 4182817, 4182818, 4182819, 4182821, 4182822, 4182823, 4182824, 4182825, 4182826, 4182800, 4182801 Change classification from "I sterile" to "IIa" of art. no. 4182705, 4182706, 4182726, 4188926
42.0	Add art. no. 4188093
43.0	Add art. no. 4182709, 4182710, 4182711
44.0	Add art. no. 4182734 Delete out of market article no. 8250855SP, 8250955SP, 4182725 Harmonize product names of the art. no. 4182700, 4182701, 4182702, 4182729, 4182730, 4188090, 4188091, 4188092 to "ProSet Cyto-Set® Mix "

Title: Declaration of Conformity - 39.05.023KIT - Cyto-Set ProSet 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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