

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
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)
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
1994-12

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
PROSET-WCS10	Intrafix®	Ila
4064010	ProSet Intrafix® SafeSet	Ila
4064011	ProSet Intrafix® SafeSet	Ila
4088549	ProSet Intrafix® Primeline	Ila
4180038	ProSet Intrafix® Primeline	Ila
4180119	ProSet Intrafix Primeline	Ila
4182001A	ProSet Intrafix® Safeset	Ila
4182002A	ProSet Intrafix® SafeSet	Ila
4182097	ProSet Intrafix® SafeSet	Ila
4182098	ProSet Intrafix® SafeSet	Ila
4182099	ProSet Discifix®C Hahnbank Set 5-fach bunt	Ila
4182100	ProSet Intrafix®	Ila
4182101	ProSet Intrafix®	Ila
4182102	ProSet Intrafix®	Ila
4182104	ProSet Intrafix®	Ila
4182105	ProSet Intrafix®	Ila
4182111	ProSet Intrafix® Primeline	Ila
4182179	ProSet Intrafix® SafeSet	Ila
4182256	ProSet Intrafix® Primeline	Ila
4182409	ProSet Intrafix® SafeSet	Ila
4182812	ProSet Infusionsset mit Spritzen und Kanülen	Ila
4183410	ProSet Intrafix® SafeSet	Ila
4183450	ProSet Intrafix® SafeSet	Ila
4183455	ProSet Intrafix® SafeSet	Ila
4183665	ProSet Intrafix® SafeSet	Ila
4183791	ProSet Intrafix® Primeline	Ila
4184321	ProSet Intrafix® SafeSet	Ila
4184661	ProSet Intrafix® SafeSet	Ila
4186087	ProSet Intrafix® Primeline	Ila
4186097	ProSet Intrafix® SafeSet	Ila
4186109	ProSet Intrafix® SafeSet	Ila
4186110	ProSet Intrafix® SafeSet	Ila
4186168	ProSet Intrafix® Primeline	Ila
4186320	ProSet Intrafix® Primeline	Ila
4186711	ProSet Intrafix® Primeline	Ila
4186914	ProSet Connection Set	Ila

4186950	ProSet Intrafix® Primeline	Ila
4186980	ProSet Intrafix® SafeSet	Ila
4186981	ProSet Intrafix® SafeSet	Ila
4187005	ProSet Intrafix® Primeline	Ila
4187006	ProSet Intrafix® SafeSet	Ila
4187007	ProSet Intrafix® Primeline	Ila
4187008	ProSet Intrafix® Primeline	Ila
4187009	ProSet Intrafix® SafeSet	Ila
4187010	ProSet Intrafix® Primeline	Ila
4187011	ProSet Intrafix® SafeSet	Ila
4187012	PROSET Intrafix® SafeSet (TIVA)	Ila
4187013	PROSET Intrafix® SafeSet (TIVA)	Ila
4187014	ProSet Intrafix®	Ila
4187015	ProSet Intrafix®	Ila
4187017	ProSet Intrafix®	Ila
4187019	ProSet Intrafix®	Ila
4187020	ProSet Intrafix®	Ila
4187021	ProSet Intrafix®	Ila
4187022	ProSet Intrafix®	Ila
4187059	ProSet Infusions-Set	Ila
4187113	ProSet Intrafix® SafeSet	Ila
4187114	ProSet Intrafix® SafeSet	Ila
4187172	ProSet Intrafix® Primeline	Ila
4187175	ProSet Intrafix® SafeSet	Ila
4187176	ProSet Intrafix®	Ila
4187177	ProSet Intrafix®	Ila
4187178	ProSet Intrafix®	Ila
4187179	ProSet Intrafix®	Ila
4187181	ProSet Intrafix®	Ila
4187334	ProSet Intrafix® Primeline	Ila
4187555	ProSet Intrafix® Primeline	Ila
4187946	ProSet Intrafix® Primeline	Ila
4187989	ProSet Intrafix® SafeSet	Ila
4188020	ProSet Intrafix® Primeline	Ila
4188030	ProSet Intrafix® SafeSet	Ila
4188110	ProSet Intrafix® SafeSet	Ila
4188113	ProSet Intrafix® SafeSet	Ila
4188114	ProSet Intrafix® SafeSet	Ila
4188115	ProSet Intrafix® SafeSet	Ila
4188116	ProSet Intrafix® SafeSet	Ila

4188117	ProSet Intrafix® SafeSet	Ila
4188120	ProSet Intrafix® SafeSet	Ila
4188136	ProSet Intrafix® SafeSet	Ila
4188137	ProSet Intrafix® SafeSet	Ila
4188138	ProSet Intrafix® SafeSet	Ila
4188140	ProSet Intrafix® SafeSet	Ila
4188155	ProSet Intrafix® SafeSet	Ila
4188159	ProSet Intrafix® SafeSet	Ila
4188170	ProSet Intrafix® SafeSet	Ila
4188530	ProSet Intrafix® SafeSet	Ila
4188531	ProSet Intrafix® SafeSet	Ila
4188540	ProSet Intrafix® SafeSet	Ila
4188550	ProSet Intrafix® SafeSet	Ila
4188551	PROSET WCS Intrafix® SafeSet	Ila
4188553	ProSet Intrafix®	Ila
4188554	ProSet Intrafix®	Ila
4188555	ProSet Intrafix®	Ila
4188556	ProSet Intrafix®	Ila
4188557	ProSet Intrafix®	Ila
4188558	ProSet Intrafix®	Ila
4188559	ProSet Intrafix®	Ila
4188560	ProSet Intrafix®	Ila
4188561	ProSet Intrafix®	Ila
4188562	ProSet Intrafix®	Ila
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4188564	ProSet Intrafix®	Ila
4188565	ProSet Intrafix®	Ila
4188566	ProSet Intrafix®	Ila
4188567	ProSet Intrafix®	Ila
4188568	ProSet Intrafix®	Ila
4188569	ProSet Intrafix®	Ila
4188570	ProSet Intrafix®	Ila
4188571	ProSet Intrafix®	Ila
4188572	ProSet Intrafix®	Ila
4188573	ProSet Intrafix®	Ila
4188574	ProSet Intrafix®	Ila
4188575	ProSet Intrafix®	Ila
4188576	ProSet Intrafix®	Ila
4188577	ProSet Intrafix®	Ila
4188578	ProSet Intrafix®	Ila

4188579	ProSet Intrafix®	Ila
4188580	ProSet Intrafix®	Ila
4188581	ProSet Intrafix®	Ila
4188582	ProSet Intrafix®	Ila
4188583	ProSet Intrafix®	Ila
4188584	ProSet Intrafix®	Ila
4188585	ProSet Intrafix®	Ila
4188586	ProSet Intrafix®	Ila
4189109	ProSet Intrafix® SafeSet	Ila
4189582	ProSet Intrafix® SafeSet	Ila

Amendment Information

Version	Description of changes
25.0	Add art. no. 4188155
26.0	Delete out of market art. no. 4187229 Delete art. no. 4188170, 4186720, 4182179, 4182002A (will be covered by DoC 39.05.001KIT)
27.0	Add article no. 4187172 (previously covered by 39.05.013KIT)
28.0	Add article no. 4188550 (previously covered by 39.05.001KIT)
29.0	Change product name of art. no. 4186914 from "ProSet Infusions-Set" to "ProSet Connection Set" Harmonize product names of art. 4186087, 4182256, 4182111, 4187555, 4187946, 4187005 no. to "ProSet Intrafix® Primeline" Harmonize product names of art. no. 4064010, 4064011, 4182098, 4182409, 4184661 to "ProSet Intrafix® SafeSet" Add art. no. 4180038, 4184321, 4186168, 4186320, 4187334, 4188020, 4182100, 4182101, 4182102, 4182104, 4182105, 4187014, 4187015, 4187017, 4187019, 4187020, 4187021, 4187022, 4187176, 4187177, 4187178, 4187179, 4187181, 4188553, 4188554, 4188555, 4188556, 4188557, 4188558, 4188559, 4188560, 4188561, 4188562, 4188563, 4188564, 4188565, 4188566, 4188567, 4188568, 4188569, 4188570, 4188571, 4188572, 4188573, 4188574, 4188575, 4188576, 4188577, 4188578, 4188579, 4188580, 4188581, 4188582, 4188583, 4188584, 4188585, 4188586, 4183791, 4183455, 4183665, 4186981, 4187175, 4187989, 4188030, 4188117, 4188540, 4182002A, 4187012, 4187013, 4188115, 4182179, 4188170, 4187007, 4188551 (previously covered by 39.05.001KIT) Add art. no. 4182097 (previously covered by 39.05.003KIT) Add art. no. 4088549, 4186711, 4186950, 4186097, 4186110, 4186980, 4187011, 4188113, 4188116, 4188138, 4189109, 4187008, 4187010 (previously covered by 39.05.050KIT)

Title: Declaration of Conformity - 39.05.005KIT - Intrafix P 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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