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

Kundenspezifische Sets
(Artikelnummern siehe Anlage I)

Customized Kits
(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)
nach Anhang VII und V
der oben genannten Richtlinie

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

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

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

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

Date of first CE-marking
1994-12

Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4061233	ProSet Extradop®-Set	I steril / I sterile
4087193	ProSet Twin Spike Vet	I steril / I sterile
4182103	ProSet Intrafix® Primeline	I steril / I sterile
4182106	ProSet Intrafix®	I steril / I sterile
4182107	ProSet Intrafix®	I steril / I sterile
4182108	ProSet Intrafix®	I steril / I sterile
4182109	ProSet Intrafix®	I steril / I sterile
4182227	ProSet Infusions-Set	I steril / I sterile
4182815	ProSet Infusions - Set	I steril / I sterile
4184188	ProSet Exadrop®Safeset	I steril / I sterile
4184239	ProSet Intrafix® SafeSe	I steril / I sterile
4186719	ProSet Exadrop®	I steril / I sterile
4186720	ProSet Exadrop®	I steril / I sterile
4186721	ProSet Exadrop®	I steril / I sterile
4186722	PROSET WCS Intrafix® SafeSet Exadrop	I steril / I sterile
4186724	ProSet Exadrop®	I steril / I sterile
4186725	ProSet Exadrop®	I steril / I sterile
4186726	ProSet Exadrop®	I steril / I sterile
4186727	ProSet Exadrop®	I steril / I sterile
4186728	ProSet Exadrop®	I steril / I sterile
4186730	ProSet Exadrop®	I steril / I sterile
4186731	ProSet Exadrop®	I steril / I sterile
4187182	ProSet Intrafix®	I steril / I sterile
4187183	ProSet Intrafix®	I steril / I sterile
4187184	ProSet Intrafix®	I steril / I sterile
4187185	ProSet Intrafix®	I steril / I sterile
4187890	ProSet Intrafix® SafeSet	I steril / I sterile
4187891	ProSet Intrafix® SafeSet	I steril / I sterile
4188095	ProSet Infusions-Set	I steril / I sterile
4188118	ProSet Intrafix® SafeSet	I steril / I sterile
4188119	ProSet Intrafix® SafeSet	I steril / I sterile
4188139	ProSet Intrafix®	I steril / I sterile
4188142	ProSet Intrafix®	I steril / I sterile
4188143	ProSet Intrafix®	I steril / I sterile
4188145	ProSet Intrafix®	I steril / I sterile
4188146	ProSet Intrafix®	I steril / I sterile
4188147	ProSet Intrafix®	I steril / I sterile

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4188148	ProSet Intrafix®	I steril / I sterile
4188149	ProSet Intrafix®	I steril / I sterile
4188150	ProSet Intrafix®	I steril / I sterile
4188151	ProSet Intrafix®	I steril / I sterile
4188153	ProSet Intrafix®	I steril / I sterile
4188154	ProSet Intrafix®	I steril / I sterile
4188552	PROSET WCS Intrafix® SafeSet	I steril / I sterile
4188587	ProSet Intrafix®	I steril / I sterile
4188588	ProSet Intrafix®	I steril / I sterile
4188589	ProSet Intrafix®	I steril / I sterile
4188590	ProSet Intrafix®	I steril / I sterile
4188591	ProSet Intrafix®	I steril / I sterile
4188592	ProSet Intrafix®	I steril / I sterile
4188593	ProSet Intrafix®	I steril / I sterile
4188594	ProSet Intrafix®	I steril / I sterile
4188595	ProSet Intrafix®	I steril / I sterile
4188596	ProSet Intrafix®	I steril / I sterile
4188597	ProSet Intrafix®	I steril / I sterile
4188598	ProSet Intrafix®	I steril / I sterile
4188599	ProSet Intrafix®	I steril / I sterile
4188600	ProSet Intrafix®	I steril / I sterile
4188601	ProSet Intrafix®	I steril / I sterile
4188602	ProSet Intrafix®	I steril / I sterile
4188603	ProSet Intrafix®	I steril / I sterile
4188604	ProSet Intrafix®	I steril / I sterile
4188605	ProSet Intrafix®	I steril / I sterile
4188606	ProSet Intrafix®	I steril / I sterile
4188607	ProSet Intrafix®	I steril / I sterile
4188608	ProSet Intrafix®	I steril / I sterile

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Amendment Information

Version	Description of changes
31.0	Add art. no. 4186720, 4188170, 4182179 formerly covered by DoC 39.05.005KIT
32.0	Add art. no. 4182002A formerly covered by DoC 39.05.005KIT
33.0	Delete art. no. 4188550 will be covered 39.05.005KIT
34.0	Change product name of art. no. 4182103 from “ProSet Infusions-Set” to “ProSet Intrafix® Primeline”
35.0	Change product name of art. no. 4186720, 4186721 from “ProSet Intrafix SafeSet Exadrop” to “ProSet Exadrop®” Delete art. no. 4187018 (streamlined) Delete art. no. 8252828 which will be covered by 39.05.03KIT Delete 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 which will be cover by 39.05.005KIT

Title: Declaration of Conformity - 39.05.001KIT - Intrafix G 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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