

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

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4081002	ProSet Infusions - Set	Ila
4180300	ProSet Discofix®C Hahnbank-Set 5-fach	Ila
4180350	ProSet Intrapur® 0,2 µm	Ila
4180351	ProSet Discofix®-C Dreivegehahnbank	Ila
4181051	ProSet Discofix® C Hahnbank Set 5-fach	Ila
4182550	ProSet Infusions-Set	Ila
4182551	ProSet Infusions-Set	Ila
4182580	ProSet Infusions-Set	Ila
4182582	ProSet Intrapur® 1,2 µm	Ila
4183240	ProSet Intrapur® Plus 0,2 µm Infusionsfilter	Ila
4183245	ProSet Intrapur® 0,2 µm	Ila
4183255	ProSet Intrapur® 0,2 µm	Ila
4183914	ProSet Intrapur® 1,2 µm	Ila
4183915	ProSet Intrapur® 0,2 µm	Ila
4183934	ProSet Infusions-Set	Ila
4183936	ProSet Intrapur® 0,2 µm	Ila
4184000	ProSet Infusions-Set	Ila
4184001	ProSet Intrapur® 1,2 µm	Ila
4184002	ProSet Infusions-Set	Ila
4184003	ProSet Intrapur® 0,2 µm	Ila
4184424	ProSet Intrapur® 1,2 µm	Ila
4184807SP	ProSet TPN Infusion Set	Ila
4187505	ProSet LS – 2 Verbinder	Ila
4187822	ProSet Intrapur® 0,2 µm	Ila
4187825	ProSet Discofix® C Hahnbank Set 3-fach	Ila

Amendment Information

Version	Description of changes
34.0	Add art. no. 4182582
35.0	Add art. no. 4184424 formerly covered by 39.05.050KIT
36.0	Delete out of market art. no. 4181052
37.0	Add art. no. 4183936 formerly covered by 39.05.009KIT Delete art. no. 4182562 and 4182555, which will be covered by 39.05.013KIT Delete art. no. 4099265, which will be covered by 39.05.009KIT Delete art. no. 4183947, 4098725, 4183913, 4184006, 4183933, 4183930, 4183935, 4184004, 4183925, 4183937, which will be covered by 39.05.003KIT Delete art. no. 4188198, 4184549, 4187529, 4182490, 4187880, 4181028, 4180120, 4182638, which will be covered by 39.05.050KIT
38.0	Harmonize product name of art. no. 4183255, 4184003, 4183915, 4180350, 4183245, 4187822 to "ProSet Intrapur® 0,2 µm" Harmonize product name of art. no. 4184001, 4183914, 4180351, 4184424, 4182582 to "ProSet Intrapur® 1,2 µm"

Title: Declaration of Conformity - 39.05.008KIT - Intrapur 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, 18 May 2021, 16:32 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Tuesday, 18 May 2021, 18:22 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Tuesday, 18 May 2021, 22:16 W. Europe Daylight Time
Meaning: Approve Document
