

**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/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang VII und V
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril
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**
2024-05-26hereby 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 VII and V
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 I sterile
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
4093089	ProSet Punktions-Set	Ila
4181221	ProSet Sterican®-Kanülen Set	Ila
4188180	ProSet Sterican®-Kanülen Set	Ila
4188200	ProSet Sterican® Set G18 (1x=10 Stück)	Ila
4188220	ProSet Sterican® Mix Set G18 (1x=10 Stück)	I steril / I sterile
4188230	ProSet Sterican® Mix Set G18 (1x=25 Stück)	I steril / I sterile
4488190	ProSet Sterican®-Kanülen Set	Ila

Amendment Information

Version	Description of changes
4.0	Delete Out of Market art. no. 4187318
5.0	Delete Out of Market art. no. 4891122
6.0	Delete Out of Market art. no. 4188181
7.0	Delete Out of Market art. no. 4187788
8.0	Add art. no. 4188220, 4188230, 4188200

Title: Declaration of Conformity -DC-39.05.220aKIT 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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Meaning: Document signed as Author

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Date: Thursday, 20 May 2021, 21:17 W. Europe Daylight Time
Meaning: Approve Document

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Meaning: Approve Document
