

**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
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**nach Anhang VII und V
der oben genannten Richtlinie**Klassifizierung**gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril**Benannte Stelle**TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**

2014-07

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 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**according to annex VII and V
of the Council Directive named above**Classification**according to annex IX of the
Council Directive named above
Class I sterile**Notified Body**TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**

2014-07

Valid until

2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4187827	ProSet Mini-Spike® Set blau (5 Stück)	Is
4187828	ProSet Mini-Spike® Chemo V Set (5 Stück)	Is
4187829	ProSet Mini-Spike® Set grün (5 Stück)	Is
4187840	ProSet Mini-Spike® Chemo V Set (1x = 20 Stück)	Is
4187850	ProSet Mini-Spike® Chemo Set (5 Stück)	Is
4187851	ProSet Mini-Spike® Chemo ST Set (5 Stück)	Is
4187855	ProSet Mini-Spike® V grün Set (5 Stück)	Is
4187860	ProSet Mini-Spike® Chemo Micro-Tip Set (1x = 5 Stück)	Is
4187870	ProSet Mini-Spike® 2 Set grün (1 x = 5 Stück)	Is

History

Version	Description of changes
3.0	Add art. no. 4187855
4.0	Add art. no. 4187840
5.0	Add art. no. 4187860, 4187870

Title: Declaration of Conformity - 39.05.004KIT - Mini-Spike 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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Date: Thursday, 20 May 2021, 14:27 W. Europe Daylight Time
Meaning: Document signed as Author

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Date: Thursday, 20 May 2021, 20:55 W. Europe Daylight Time
Meaning: Approve Document

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Meaning: Approve Document
