

**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/ehereby 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
1993Council Directive 93/42/EEC of 14th June
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EGconcerning Medical Devices
amended by Directive 2007/47/EC**Konformitätsbewertungsverfahren**
nach Anhang VII und V
der oben genannten Richtlinie**Conformity Assessment Procedure**
according to annex VII and V
of the Council Directive named above**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril Messfunktion**Classification**
according to annex IX of the
Council Directive named above
Class I sterile measuring function**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**
1996-03**Date of first CE-marking**
1996-03**Gültig bis**
2024-05-26**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4183207	ProSet Spritzen-Set	I steril Messfunktion / I sterile measuring function
4187210	ProSet Injekt® Spritzen-Set	I steril Messfunktion / I sterile measuring function
4187230	ProSet Injekt®-Spritzen Set	I steril Messfunktion / I sterile measuring function
4187250	ProSet Injekt® Spritzen-Set	I steril Messfunktion / I sterile measuring function
4187260	ProSet Injekt®-Spritzen Set (1x = 5 Stück) 20ml Luer-Steck	I steril Messfunktion / I sterile measuring function
4187571	ProSet Spritzen-Set	I steril Messfunktion / I sterile measuring function
4187572	ProSet Spritzen-Set	I steril Messfunktion / I sterile measuring function
4187573	ProSet Injekt® Spritzen Set (1x = 20 Stück)	I steril Messfunktion / I sterile measuring function
4187594	ProSet Injekt®-Spritzen Set (20Stück)	I steril Messfunktion / I sterile measuring function
4187595	ProSet Injekt®-Spritzen Set	I steril Messfunktion / I sterile measuring function
4187596	ProSet Injekt®-Spritzen Set	I steril Messfunktion / I sterile measuring function

Amendment Information

Version	Description of changes
8.0	Delete out of market art. no. 4457099
9.0	Delete out of market art. no. 4182686
10.0	Update validity
11.0	Change product name of art. no. 4187573 from "ProSet Injekt®-Spritzen Set" to "ProSet Injekt® Spritzen Set (1x = 20 Stück)"
12.0	Add art. no. 4187260

Title: Declaration of Conformity - 094-002KIT - Injekt 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: Thursday, 20 May 2021, 14:11 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 20 May 2021, 20:57 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Friday, 21 May 2021, 14:53 W. Europe Daylight Time
Meaning: Approve Document
