

**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 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**
2024-05-26hereby 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 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**Effective**

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4206002	Ventilkanüle 1,3 x 73 mm, 18G	Ila
4206088	Seldinger Kanüle	Ila
4206096	Seldinger Kanüle	Ila
4206100	Seldinger Kanüle	Ila
4206118	Seldinger Kanüle	Ila
4206606	Seldinger Kanüle	Ila

Amendment Information

Version	Description of the changes
09	Update validity
08	Due to article 12 of the MDD 93/42/EEC article codes 4209486, 4462033 switched to Manufacturers Declaration 279-100aKIT
07	Update TÜV address

Title: Declaration of Conformity - 39.05.103KIT - Introducer needle Initiator: Sandra ? Staufenberg

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Staufenberg, Sandra (stausade)
Title: Administrator Regulatory Affairs CoE Pain Control & CVC
Date: Thursday, 16 April 2020, 11:58 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Goebel, Udo (goebudde)
Title: HC-RA-DE08E Head of RA Pain Control & CVC
Date: Thursday, 16 April 2020, 12:25 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 16 April 2020, 20:12 W. Europe Daylight Time
Meaning: Approve Document
