

**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**Triple Set, Twin Set,
Venofix®, Venofix® A**

Venenpunktionkanülen

(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 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**
Venofix®, Venofix® A1994-12
Twin Set, Triple Set 2007-07**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Triple Set, Twin Set,
Venofix®, Venofix® A**

Venipuncture Sets

(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 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**
Venofix®, Venofix® A1994-12
Twin Set, Triple Set 2007-07**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4047630	Venofix®	Ila
4047641	Twin Set	Ila
4047642	Triple Set	Ila
4056310	Venofix® A	Ila
4056337	Venofix® A	Ila
4056345	Venofix® A	Ila
4056353	Venofix® A	Ila
4056361	Venofix® A	Ila
4056370	Venofix® A	Ila
4056388	Venofix® A	Ila

Amendment Information

Version	Description of the changes
16	Delete Out of Market article no. 4050186
17	Delete Out of Market article no. 4048067, 4048083, 4048091, 4048075
18	Delete Out of Market article no. 0005552K
19	Delete Out of Market article no. 4048059

Title: Declaration of Conformity - 39.05.101 - Venofix 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: Monday, 06 January 2020, 09:42 W. Europe Daylight Time
Meaning: Document signed as Author

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Date: Tuesday, 07 January 2020, 08:10 W. Europe Daylight Time
Meaning: Approve Document

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Date: Tuesday, 07 January 2020, 08:28 W. Europe Daylight Time
Meaning: Approve Document
