

**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**Vasofix® Safety**

Venenverweilkanülen

(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**Vasofix® Safety**

I. V. cannulae

(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

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4268091S	Vasofix® Safety	Ila
4268091S-01	Vasofix® Safety	Ila
4268091S-03	Vasofix® Safety	Ila
4268113S-01	Vasofix® Safety	Ila
4268113S-03	Vasofix® Safety	Ila
4268130S	Vasofix® Safety	Ila
4268130S-01	Vasofix® Safety	Ila
4268130S-03	Vasofix® Safety	Ila
4268156S-01	Vasofix® Safety	Ila
4268156S-03	Vasofix® Safety	Ila
4268172S	Vasofix® Safety	Ila
4268172S-01	Vasofix® Safety	Ila
4268172S-03	Vasofix® Safety	Ila
4268210S	Vasofix® Safety	Ila
4268210S-01	Vasofix® Safety	Ila
4268210S-03	Vasofix® Safety	Ila
4268334S	Vasofix® Safety	Ila
4268334S-01	Vasofix® Safety	Ila
4268334S-03	Vasofix® Safety	Ila
4269071S-01	Vasofix® Safety	Ila
4269071S-03	Vasofix® Safety	Ila
4269071S-20	Vasofix® Safety	Ila
4269071SIN	Vasofix® Safety	Ila
4269098S-01	Vasofix® Safety	Ila
4269098S-03	Vasofix® Safety	Ila
4269098S-20	Vasofix® Safety	Ila
4269098SIN	Vasofix® Safety	Ila
4269110S-01	Vasofix® Safety	Ila
4269110S-03	Vasofix® Safety	Ila
4269110S-20	Vasofix® Safety	Ila
4269110SIN	Vasofix® Safety	Ila
4269136S	Vasofix® Safety	Ila
4269136S-01	Vasofix® Safety	Ila
4269136S-03	Vasofix® Safety	Ila
4269136S-20	Vasofix® Safety	Ila
4269136SIN	Vasofix® Safety	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4269152S	Vasofix® Safety	Ila
4269152S-01	Vasofix® Safety	Ila
4269152S-03	Vasofix® Safety	Ila
4269152S-20	Vasofix® Safety	Ila
4269179S	Vasofix® Safety	Ila
4269179S-01	Vasofix® Safety	Ila
4269179S-03	Vasofix® Safety	Ila
4269179S-20	Vasofix® Safety	Ila
4269179SIN	Vasofix® Safety	Ila
4269217S-01	Vasofix® Safety	Ila
4269217S-03	Vasofix® Safety	Ila
4269217S-20	Vasofix® Safety	Ila
4269225S	Vasofix® Safety	Ila
4269225S-01	Vasofix® Safety	Ila
4269225S-03	Vasofix® Safety	Ila
4269225S-20	Vasofix® Safety	Ila
4269330S	Vasofix® Safety	Ila
4269330S-01	Vasofix® Safety	Ila
4269330S-03	Vasofix® Safety	Ila
4269330S-20	Vasofix® Safety	Ila

Amendment Information

Version	Description of the changes
07	Delete Out of Market Art. No. 4269110S
08	Update validity
09	Addition of article numbers: 4269179SIN, 4269136SIN, 4269110SIN, 4269098SIN, 4269071SIN No change of product and packaging, only different printing.

Title: Declaration of Conformity - 120-030 - Vasofix Safety Initiator: Marie Fischer

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

UserName: Fischer, Marie (fiscm3de)
Title: Administrator RA International CoE Infusion & Pain Therapy
Date: Wednesday, 10 May 2023, 10:24 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: Friday, 12 May 2023, 17:39 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Tuesday, 16 May 2023, 17:57 W. Europe Daylight Time
Meaning: Approve Document
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