

**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  
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**  
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 14<sup>th</sup> 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**  
1994-12**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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
4269098S-01	Vasofix® Safety	Ila
4269098S-03	Vasofix® Safety	Ila
4269098S-20	Vasofix® Safety	Ila
4269110S-01	Vasofix® Safety	Ila
4269110S-03	Vasofix® Safety	Ila
4269110S-20	Vasofix® Safety	Ila
4269136S	Vasofix® Safety	Ila
4269136S-01	Vasofix® Safety	Ila
4269136S-03	Vasofix® Safety	Ila
4269136S-20	Vasofix® Safety	Ila
4269152S	Vasofix® Safety	Ila
4269152S-01	Vasofix® Safety	Ila
4269152S-03	Vasofix® Safety	Ila
4269152S-20	Vasofix® Safety	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4269179S	Vasofix® Safety	Ila
4269179S-01	Vasofix® Safety	Ila
4269179S-03	Vasofix® Safety	Ila
4269179S-20	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
06	Delete Out of Market Art. No. 4268113S, 4268156S, 4269071S, 4269217S, 4269098S
07	Delete Out of Market Art. No. 4269110S
08	Update validity

Title: Declaration of Conformity - 120-030 - Vasofix Safety 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: Tuesday, 31 March 2020, 07:54 W. Europe Daylight Time  
Meaning: Document signed as Author

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UserName: Brand, Thomas (brantode)  
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Meaning: Approve Document

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UserName: Seidel, Stefan (seidstde)  
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems  
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Meaning: Approve Document

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