

**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 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**
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
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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Tuesday, 31 March 2020, 21:28 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Thursday, 02 April 2020, 09:55 W. Europe Daylight Time
Meaning: Approve Document

Dichiarazione di conformità

Noi,

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germania

dichiariamo sotto la nostra responsabilità che il/i prodotto/i

Vasofix® Safety

Cannule I.V.

(per i codici prodotto vedasi allegato I)

sono conformi alla seguente direttiva

Direttiva Europea 93/42/CEE del 14 giugno 1993
sui dispositivi medici
modificata dalla Direttiva 2007/47/CE

Procedura di valutazione della conformità
secondo l'allegato II (esclusa la sezione 4)
della Direttiva del Consiglio sopra menzionata

Classificazione
secondo l'allegato IX
della Direttiva sopra menzionata
Classe IIa

Ente Notificatore
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 Monaco
Germania
Numero identificativo 0123

Data prima marcatura CE
1994-12

Valido fino al
26-05-2024

ALLEGATO I

No. Articolo	Nome prodotto	Classe
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
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4268156S-03	Vasofix® Safety	Ila
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4269136S-03	Vasofix® Safety	Ila
4269136S-20	Vasofix® Safety	Ila
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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
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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

Informazioni sulle modifiche

Revisione	Descrizione del cambiamento
06	Eliminazione fuori mercato art. 4268113S, 4268156S, 4269071S, 4269217S, 4269098S
07	Eliminazione fuori mercato art. 4269110S
08	Aggiornamento validità