Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung, dass das/die Produkt/e

hereby declare in our own responsibility that the product/s

Vasofix® Safety
Venenverweilkanülen

Vasofix® Safety
I. V. cannulae

(Artikelnummern und Basic UDI-DI siehe Anlage I)

(article numbers and Basic UDI-DI see attachment I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmt/übereinstimmen

is/are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse IIa

Classification
according to annex VIII of the Regulation named above
Class IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Gültig bis
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)

Valid until
according to our valid EU Certificate
(No. G10 012974 0611)

Effective

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Anlage I / Attachment I

Basic UDI-DI: 40392390000007642U

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
---	**Vasofix® Safety FEP (European Labelling - 01)**	---
4268091S-01	Vasofix® Safety	IIa
4268113S-01	Vasofix® Safety	IIa
4268130S-01	Vasofix® Safety	IIa
4268334S-01	Vasofix® Safety	IIa
4268156S-01	Vasofix® Safety	IIa
4268172S-01	Vasofix® Safety	IIa
4268210S-01	Vasofix® Safety	IIa
---	**Vasofix® Safety PUR (European Labelling - 01)**	---
4269071S-01	Vasofix® Safety	IIa
4269098S-01	Vasofix® Safety	IIa
4269110S-01	Vasofix® Safety	IIa
4269217S-01	Vasofix® Safety	IIa
4269136S-01	Vasofix® Safety	IIa
4269330S-01	Vasofix® Safety	IIa
4269152S-01	Vasofix® Safety	IIa
4269179S-01	Vasofix® Safety	IIa
4269225S-01	Vasofix® Safety	IIa
---	**Vasofix® Safety FEP (Asia Pacific Labelling - 03)**	---
4268091S-03	Vasofix® Safety	IIa
4268113S-03	Vasofix® Safety	IIa
4268130S-03	Vasofix® Safety	IIa
4268334S-03	Vasofix® Safety	IIa
4268156S-03	Vasofix® Safety	IIa
4268172S-03	Vasofix® Safety	IIa
4268210S-03	Vasofix® Safety	IIa
---	**Vasofix® Safety PUR (Asia Pacific Labelling - 03)**	---
4269071S-03	Vasofix® Safety	IIa
4269098S-03	Vasofix® Safety	IIa
4269110S-03	Vasofix® Safety	IIa
4269217S-03	Vasofix® Safety	IIa
4269136S-03	Vasofix® Safety	IIa
4269330S-03	Vasofix® Safety	IIa
4269152S-03	Vasofix® Safety	IIa
4269179S-03	Vasofix® Safety	IIa
4269225S-03	Vasofix® Safety	IIa

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Anlage I / Attachment I

Basic UDI-DI: 40392390000007642U

---	**Vasofix® Safety PUR (CIS Labelling - 20)**	---
4269071S-20	Vasofix® Safety	IIa
4269098S-20	Vasofix® Safety	IIa
4269110S-20	Vasofix® Safety	IIa
4269217S-20	Vasofix® Safety	IIa
4269136S-20	Vasofix® Safety	IIa
4269330S-20	Vasofix® Safety	IIa
4269152S-20	Vasofix® Safety	IIa
4269179S-20	Vasofix® Safety	IIa
4269225S-20	Vasofix® Safety	IIa
---	**Vasofix® Safety PUR (India Labelling - IN)**	---
4269179SIN	Vasofix® Safety	IIa
4269136SIN	Vasofix® Safety	IIa
4269110SIN	Vasofix® Safety	IIa
4269098SIN	Vasofix® Safety	IIa
4269071SIN	Vasofix® Safety	IIa

Basic UDI-DI: 40392390000030462C (Vasofix Safety EBEAM)

4269071SR-01	Vasofix® Safety	IIa
4269098SR-01	Vasofix® Safety	IIa
4269110SR-01	Vasofix® Safety	IIa
4269136SR-01	Vasofix® Safety	IIa
4269152SR-01	Vasofix® Safety	IIa
4269179SR-01	Vasofix® Safety	IIa
4269217SR-01	Vasofix® Safety	IIa
4269225SR-01	Vasofix® Safety	IIa
4269330SR-01	Vasofix® Safety	IIa

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Document amendment information

Version	Description of the changes
2.0	Update Vasofix Safety EBEAM Sterilization; Basic UDI-DI: 40392390000030462; project F.407-21IV.01
1.0	Initial Version

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Title: Declaration of Conformity 120-030 - Vasofix Safety - MDR Initiator: Ulrich ? Jedelhauser

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

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