

**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

Vasofix® Safety
Venenverweilkanülen

(Artikelnummern und Basic UDI-DI siehe Anlage I)

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

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

hereby declare in our own responsibility
that the product/s

Vasofix® Safety
I. V. cannulae

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

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

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

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

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

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

Effective

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	Ila
4268113S-01	Vasofix® Safety	Ila
4268130S-01	Vasofix® Safety	Ila
4268334S-01	Vasofix® Safety	Ila
4268156S-01	Vasofix® Safety	Ila
4268172S-01	Vasofix® Safety	Ila
4268210S-01	Vasofix® Safety	Ila
---	Vasofix® Safety PUR (European Labelling - 01)	---
4269071S-01	Vasofix® Safety	Ila
4269098S-01	Vasofix® Safety	Ila
4269110S-01	Vasofix® Safety	Ila
4269217S-01	Vasofix® Safety	Ila
4269136S-01	Vasofix® Safety	Ila
4269330S-01	Vasofix® Safety	Ila
4269152S-01	Vasofix® Safety	Ila
4269179S-01	Vasofix® Safety	Ila
4269225S-01	Vasofix® Safety	Ila
---	Vasofix® Safety FEP (Asia Pacific Labelling - 03)	---
4268091S-03	Vasofix® Safety	Ila
4268113S-03	Vasofix® Safety	Ila
4268130S-03	Vasofix® Safety	Ila
4268334S-03	Vasofix® Safety	Ila
4268156S-03	Vasofix® Safety	Ila
4268172S-03	Vasofix® Safety	Ila
4268210S-03	Vasofix® Safety	Ila
---	Vasofix® Safety PUR (Asia Pacific Labelling - 03)	---
4269071S-03	Vasofix® Safety	Ila
4269098S-03	Vasofix® Safety	Ila
4269110S-03	Vasofix® Safety	Ila
4269217S-03	Vasofix® Safety	Ila
4269136S-03	Vasofix® Safety	Ila
4269330S-03	Vasofix® Safety	Ila
4269152S-03	Vasofix® Safety	Ila
4269179S-03	Vasofix® Safety	Ila
4269225S-03	Vasofix® Safety	Ila

Anlage I / Attachment I

Basic UDI-DI: 40392390000007642U

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

Document amendment information

Version	Description of the changes
1.0	Initial Version

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:

UserName: Jedelhauser, Ulrich (jedeulde)

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Date: Friday, 03 May 2024, 15:05 W. Europe Daylight Time

Meaning: Document signed as Author

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UserName: Seidel, Stefan (seidstde)

Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy

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Date: Friday, 03 May 2024, 17:14 W. Europe Daylight Time

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