

**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)

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: 4039239000007642U

---	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:

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