

**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 die Produkte**Perifix® Filter 0.2 µm,
Perifix® Filter 0.2 µm NRFit®**
Filter für die RegionalanästhesieBasis UDI-DI 403923900000238834
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 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
(G10 012974 0611)hereby declare in our sole responsibility
that the products**Perifix® Filter 0.2 µm,
Perifix® Filter 0.2 µm NRFit®**
Filter for Regional AnesthesiaBasic UDI-DI 403923900000238834
(article numbers and see attachment I)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
(G10 012974 0611)

Anlage I / Attachment I**Basic UDI-DI 403923900000238834**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4515501	Perifix [®] Filter 0.2 µm	Ila
4515501N-01	Perifix [®] Filter 0.2 µm NRFit [®]	Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR based on change HC-CHC-M-DIV-1792
2.0	Update acc. to latest template (Doc ID: BPP-HC-DIV-002413 Version: 4.0) – removal of validity date

Title: Declaration of Conformity - 196-098-MDR - Perifix Filter Initiator: Mandy Doreen ? Kleinwechter

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

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Effective