

**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® Catheter
Perifix® Catheter NRFit®****Perifix® SoftTip Catheter
Perifix® SoftTip Catheter NRFit®****Perifix® ONE Catheter
Perifix® ONE Catheter NRFit®**

Epiduralkatheter

Basis UDI-DI 40392390000023832S
(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 III**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigen EU Zertifikaten
(Nr. G70 012974 0631
Nr. G12 012974 0651)hereby declare in our own responsibility
that the products**Perifix® Catheter
Perifix® Catheter NRFit®****Perifix® SoftTip Catheter
Perifix® SoftTip Catheter NRFit®****Perifix® ONE Catheter
Perifix® ONE Catheter NRFit®**

Epidural catheter

Basic UDI-DI 40392390000023832S
(article numbers 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 III**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**
according to our valid EU Certificates
(No. G70 012974 0631
No. G12 012974 0651)

Anlage I / Attachment I**Basic UDI-DI 40392390000023832S**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4513150	Perifix® Catheter	III
4513150N-01	Perifix® Catheter NRFit®	III
4513150C	Perifix® ONE Catheter	III
45131501N-01	Perifix® ONE Catheter NRFit®	III
4513177	Perifix® Catheter	III
4513177N-01	Perifix® Catheter NRFit®	III
4513258	Perifix® Catheter	III
4513258N-01	Perifix® Catheter NRFit®	III
4513258C	Perifix® ONE Catheter	III
45132581N-01	Perifix® ONE Catheter NRFit®	III
4515048	Perifix® SoftTip Catheter	III
4515048N-01	Perifix® SoftTip Catheter NRFit®	III

Document amendment information

Version	Description of the changes
1.0	Initial version under 2017/745 MDR
2.0	Addition of G70 012974 0631 Certificate. Correction of product name "SoftTip": Deletion of space between Soft and Tip

Title: Declaration of Conformity - 190-099-MDR - Perifix Catheter Initiator: Nadine ? Knatz

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

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