

**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® Soft Tip Catheter  
Perifix® Soft Tip 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 gültigem EU Zertifikat  
(Nr. G12 012974 0651)hereby declare in our own responsibility  
that the products**Perifix® Catheter  
Perifix® Catheter NRFit®  
Perifix® Soft Tip Catheter  
Perifix® Soft Tip 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 Certificate  
(No. G12 012974 0651)

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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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® Soft Tip Catheter	III
4515048N-01	Perifix® Soft Tip Catheter NRFit®	III

### Document amendment information

Version	Description of the changes
1.0	Initial version under 2017/745 MDR

Title: Declaration of Conformity - 190-099-MDR - Perifix Catheter Initiator: Stefan ? Wuttig

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

UserName: Wuttig, Stefan (wuttstde)  
Title: HC-RA-DE08 Senior Regulatory Affairs Manager  
Date: Friday, 10 May 2024, 11:23 W. Europe Daylight Time  
Meaning: Document signed as Author

---

UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Saturday, 11 May 2024, 21:23 W. Europe Daylight Time  
Meaning: Approve Document

---

UserName: Seidel, Stefan (seidstde)  
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy  
Date: Monday, 13 May 2024, 08:23 W. Europe Daylight Time  
Meaning: Approve Document

---