

**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 Fixation
Perifix® Catheter Fixation Cover**

Fixierhilfe

(Artikelnummern und Basic UDI-DI 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 I steril**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis 2026-12-14**
gemäß gültigem EC Zertifikat
G11 012974 0626hereby declare in our own responsibility
that the products**Perifix® Catheter Fixation
Perifix® Catheter Fixation Cover**

Fixation device

(article numbers and Basic UDI-DI 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 I sterile**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until 2026-12-14**
according to our valid EC Certificate
G11 012974 0626

Anlage I / Attachment I

Basic UDI-DI 40392390000023852W

Art.-Nr. / Art. No.	Produktname / Product name
4511200	Perifix® Catheter Fixation

Klasse / Class
Is

Basic UDI-DI 40392390000027943K

Art.-Nr. / Art. No.	Produktname / Product name
4511201	Perifix® Catheter Fixation Cover

Klasse / Class
Is

Document amendment information

Version	Description of the changes
1.0	First issue of DoC acc. to MDR replacing DoC acc. to MDD, document no.: 39.05.156, version 25.0

Title: Declaration of Conformity - 196-005-MDR - Perifix Catheter Fixation Initiator: Sandra ? Staufenberg

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

UserName: Staufenberg, Sandra (stausade)
Title: Administrator Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 29 March 2023, 14:07 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 30 March 2023, 09:06 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 30 March 2023, 13:28 W. Europe Daylight Time
Meaning: Approve Document
=====