

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 Produkte

Perifix® Catheter Connector
Perifix® Catheter Connector NRFit®
Katheterkupplung für die Regionalanästhesie

Basis UDI-DI: 403923900000238732
(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® Catheter Connector
Perifix® Catheter Connector NRFit®
Catheter Connector for Regional Anesthesia

Basic UDI-DI: 403923900000238732
(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 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 403923900000238732

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4513800	Perifix® Catheter Connector	Ila
4513800N-01	Perifix® Catheter Connector NRFit®	Ila
4513801	Perifix® Catheter Connector	Ila
4513801N-01	Perifix® Catheter Connector 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-1791
2.0	Update acc. to latest template (Doc ID: BPP-HC-DIV-002413 Version: 4.0) – removal of validity date

Title: Declaration of Conformity - 196-096-MDR - Perifix Catheter Connector Initiator: Mandy Doreen ? Kleinwechter

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

UserName: Kleinwechter, Mandy Doreen (kleimnde)
Title: Regulatory Affairs Manager
Date: Tuesday, 11 March 2025, 18:33 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Seidel, Stefan (seidstde)
Title: Vice President Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 12 March 2025, 07:51 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 12 March 2025, 08:31 W. Europe Daylight Time
Meaning: Approve Document
=====

Effective