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 Produkt / die Produkte

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

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis 2025-03-12
gemäß gültigem EU Zertifikat
(G10 012974 0611)

hereby declare in our sole responsibility that the product/s

Perifix® Catheter Connector
Perifix® Catheter Connector NRFit®
Catheter Connector for Regional Anesthesia
(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 IIa

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until 2025-03-12
according to our valid EU Certificate
(G10 012974 0611)

Effective

Anlage I / Attachment I

Basic UDI-DI 403923900000238732

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4513800	Perifix® Catheter Connector	IIa
4513800N-01	Perifix® Catheter Connector NRFit®	IIa
4513801	Perifix® Catheter Connector	IIa
4513801N-01	Perifix® Catheter Connector NRFit®	IIa

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR based on change HC-CHC-M-DIV-1791

Title: Declaration of Conformity - 196-096-MDR - Perifix Catheter Connector 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: Thursday, 01 February 2024, 07:45 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 08 February 2024, 08:53 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, 08 February 2024, 08:57 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective