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® LOR
Perifix® LOR NRFit®
Spritze für die Loss-of-Resistance (LOR)-Methode in der Regionalanästhesie

Basis UDI-DI: 403923900000238936
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmen

Konformitätsbewertungsverfahren
nach Anhang IX

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I steril

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültigem EU-Zertifikat
(Nr. G11 012974 0626)

hereby declare in our sole responsibility that the products

Perifix® LOR
Perifix® LOR NRFit®
Loss of Resistance (LOR) device for use in Regional Anesthesia

Basic UDI-DI: 403923900000238936
(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

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
according to our valid EU Certificate
(No. G11 012974 0626)

Effective

Anlage I / Attachment I

Basic UDI-DI: 403923900000238936

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4637100	Perifix® LOR	Is (sterile)
4637110	Perifix® LOR NRFit®	Is (sterile)
4638107	Perifix® LOR	Is (sterile)
4638110	Perifix® LOR NRFit®	Is (sterile)

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR
2.0	Update acc. to latest template (Doc ID: BPP-HC-DIV-002413 Version: 4.0) – removal of validity date

Title: Declaration of Conformity - 196-099-MDR - Perifix LOR Initiator: Mandy Doreen ? Kleinwechter

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

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