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

Omnifix® Slip
Omnifix®-F Slip
3-piece Single-use Syringe with Slip connector without needle for Regional Anaesthesia Type NRFit®
Basis UDI-DI: 403923900000026423
(Artikelnummern siehe Anlage I)

Omnifix® Lock
3-piece Single-use Syringe with Lock connector without needle for Regional Anaesthesia Type NRFit®
Basis UDI-DI: 4039239000000044ZG
(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 I steril Messfunktion
oder
Klasse IIa

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

hereby declare in our own responsibility
that the products

Omnifix® Slip
Omnifix®-F Slip
3-piece Single-use Syringe with Slip connector without needle for Regional Anaesthesia Type NRFit®
Basic UDI-DI: 403923900000026423
(article numbers see attachment I)

Omnifix® Lock
3-piece Single-use Syringe with Lock connector without needle for Regional Anaesthesia Type NRFit®
Basic UDI-DI: 4039239000000044ZG
(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 I sterile measuring function
or
Class IIa

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Effective

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Gültig bis	**Valid until**
gemäß gültiger EU Zertifikate G11 012974 0626 (Klasse I steril Messfunktion) oder G10 012974 0611 (Klasse IIa)	according to our valid EU Certificates G11 012974 0626 (class I sterile measuring function) or G10 012974 0611 (class IIa)

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Anlage I / Attachment I

Basic UDI-DI 403923900000026423

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4616003	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
4616005	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
4616014	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
4616021	Omnifix® Slip	I steril Messfunktion / I sterile measuring function
9164001	Omnifix®-F Slip	I steril Messfunktion / I sterile measuring function

Basic UDI-DI 4039239000000044ZG

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4617003	Omnifix® Lock	IIa
4617006	Omnifix® Lock	IIa
4617014	Omnifix® Lock	IIa
4617021	Omnifix® Lock	IIa
4617508F-01	Omnifix® Lock	IIa

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Document amendment information

Version	Description of the changes
1.0	Initial Version under Medical Device Regulation (EU) 2017/745.
2.0	Addition of article code 4617508F-01
3.0	Correction of article code from 4167021 to 4617021

Effective

Title: Declaration of Conformity - 094-008 - MDR - Omnifix NRFit Initiator: Katharina Berlinecke

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

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Meaning: Document signed as Author
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