Konformitätserklärung
Declaration of Conformity

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e

hereby declare in our own responsibility
that the product/s

Perifix® Filter 0,2 µm
Filter für die Regionalanästhesie
Perifix® Filter 0,2 µm NRFit®
Filter für die Regionalanästhesie
Perifix® Catheter Connector
Katheterkupplung für die Regionalanästhesie
Perifix® Catheter Connector NRFit®
Katheterkupplung für die Regionalanästhesie
Perifix® LOR, Perifix® LOR NRFit®
Spritze für die Regionalanästhesie
Perifix® Catheter Fixation
Fixierhilfe
Perifix® Catheter Fixation Cover
Fixierhilfe

Perifix® Filter 0.2 µm
Filter for Regional Anaesthesia
Perifix® Filter 0.2 µm NRFit®
Filter for Regional Anaesthesia
Perifix® Catheter Connector
Catheter Connector for Regional Anaesthesia
Perifix® Catheter Connector NRFit®
Catheter Connector for Regional Anaesthesia
Perifix® LOR, Perifix® LOR NRFit®
Syringe for Regional Anaesthesia
Perifix® Catheter Fixation
Fixation device
Perifix® Catheter Fixation Cover
Fixation device

(Artikelnummern siehe Anlage I)

(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
nach Anhang VII und V
der oben genannten Richtlinie

Conformity Assessment Procedure
according to annex II (excluding section 4)
according to annex VII and V
of the Council Directive named above

Klassifizierung
gemäß Anhang IX
der oben genannten Richtlinie
Klasse IIa
Klasse I steril

Classification
according to annex IX
of the Council Directive named above
Class IIa
Class I sterile

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Datum der ersten CE-Kennzeichnung
Perifix® Filter 0,2 µm
Perifix® LOR
2000-10
Perifix® Catheter Connector
2001-05
Perifix® Catheter Fixation
Perifix® Catheter Fixation Cover
2004-08
Perifix LOR NRFit®
2017-11
Perifix Catheter Connector NRFit®
Perifix® Filter 0,2 µm NRFit®
2018-02

Gültig bis

2024-05-26

Date of first CE-marking
Perifix® Filter 0.2 µm
Perifix® LOR
2000-10
Perifix® Catheter Connector
2001-05
Perifix® Catheter Fixation
Perifix® Catheter Fixation Cover
2004-08
Perifix LOR NRFit®
2017-11
Perifix Catheter Connector NRFit®
Perifix® Filter 0.2 µm NRFit®
2018-02

Valid until

2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
4511200	Perifix® Catheter Fixation	I steril / I sterile
4511201	Perifix® Catheter Fixation Cover	I steril / I sterile
4513800	Perifix® Catheter Connector	IIa
4513800N-01	Perifix® Catheter Connector NRFit®	IIa
4513801	Perifix® Catheter Connector	IIa
4513801N-01	Perifix® Catheter Connector NRFit®	IIa
4513900	Perifix® Catheter Connector	IIa
4515501	Perifix® Filter 0,2 µm	IIa
4515501N-01	Perifix Filter 0,2 µm NRFit®	IIa
4637100	Perifix® LOR	I steril / I sterile
4637110	Perifix® LOR NRFit®	I steril / I sterile
4638107	Perifix® LOR	I steril / I sterile
4638110	Perifix® LOR NRFit®	I steril / I sterile

Amendment Information

Version	Description of the changes
25	Delete “out of market” article codes 4637120, 4638120
24	Delete “out of market” article codes 4513801S, 4515501S due to DIV-1541 Phase out Neuraxial SafeConnect products
23	Addition of article code 4515501N-01, because forgot to list in last version
22	Reopening article codes 4515501, 4515501N-01, 4515501S, 4637100, 4638107, 4637110, 4637120, 4638110, 4638120. Splitting will be done successivly as soon as MDR conformity reached for each product
21	Delete article codes 4515501, 4515501N-01, 4515501S, 4637100, 4638107, 4637110, 4637120, 4638110, 4638120 due to required splitting of RMF 196-001 to RMF 196-098 and RMF 196-099 acc. to new MDR rules

Title: Declaration of Conformity - 39.05.156 - RA-Accessories 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 Pain Control & CVC
Date: Tuesday, 09 February 2021, 09:22 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Tuesday, 09 February 2021, 16:58 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Grosser, Simone (donnside)
Title: Manager Regulatory Affairs
Date: Wednesday, 10 February 2021, 06:52 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective