

**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**Perifix® Filter 0,2 µm**

Filter für die Regionalanästhesie

**Perifix® Filter 0,2 µm NRFit®**

Filter für die Regionalanästhesie

**Perifix® Filter 0,2 µm SafeConnect®**

Filter für die Regionalanästhesie

**Perifix® Catheter Connector**

Katheterkupplung für die Regionalanästhesie

**Perifix® Catheter Connector NRFit®**

Katheterkupplung für die Regionalanästhesie

**Perifix® Catheter Connector SafeConnect®**

Katheterkupplung für die Regionalanästhesie

**Perifix® LOR, Perifix® LOR NRFit®**

Spritze für die Regionalanästhesie

**Perifix® Catheter Fixation**

Fixierhilfe

**Perifix® Catheter Fixation Cover**

Fixierhilfe

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie  
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni  
1993

über Medizinprodukte

geändert durch Richtlinie 2007/47/EG

**Konformitätsbewertungsverfahren**

nach Anhang II (ausgenommen Abschnitt 4)

nach Anhang VII und V

der oben genannten Richtlinie

hereby declare in our own responsibility  
that the product/s**Perifix® Filter 0.2 µm**

Filter for Regional Anaesthesia

**Perifix® Filter 0.2 µm NRFit®**

Filter for Regional Anaesthesia

**Perifix® Filter 0.2 µm SafeConnect**

Filter for Regional Anaesthesia

**Perifix® Catheter Connector**

Catheter Connector for Regional Anaesthesia

**Perifix® Catheter Connector NRFit®**

Catheter Connector for Regional Anaesthesia

**Perifix® Catheter Connector SafeConnect®**

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

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993  
concerning Medical Devices  
amended by Directive 2007/47/EC**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 Filter 0,2 µm SafeConnect®  
Perifix® Catheter Connector SafeConnect®  
2013-01  
Perifix LOR NRFit®  
2017-11  
Perifix Catheter Connector NRFit®  
Perifix® Filter 0,2 µm NRFit®  
2018-02

**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 Filter 0.2 µm SafeConnect®  
Perifix® Catheter Connector SafeConnect®  
2013-01  
Perifix LOR NRFit®  
2017-11  
Perifix Catheter Connector NRFit®  
Perifix® Filter 0.2 µm NRFit®  
2018-02

**Gültig bis**  
2024-05-26

**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. no.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4511200	Perifix® Catheter Fixation	I steril / I sterile
4511201	Perifix® Catheter Fixation Cover	I steril / I sterile
4513800	Perifix® Catheter Connector	Ila
4513800N-01	Perifix® Catheter Connector NRFit®	Ila
4513801	Perifix® Catheter Connector	Ila
4513801N-01	Perifix® Catheter Connector NRFit®	Ila
4513801S	Perifix® Catheter Connector SafeConnect®	Ila
4513900	Perifix® Catheter Connector	Ila
4515501	Perifix® Filter 0,2 µm	Ila
4515501N-01	Perifix Filter 0,2 µm NRFit®	Ila
4515501S	Perifix® Filter 0,2 µm SafeConnect®	Ila
4637100	Perifix® LOR	I steril / I sterile
4637110	Perifix® LOR NRFit®	I steril / I sterile
4637120	Perifix® LOR NRFit®	I steril / I sterile
4638107	Perifix® LOR	I steril / I sterile
4638110	Perifix® LOR NRFit®	I steril / I sterile
4638120	Perifix® LOR NRFit®	I steril / I sterile

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
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
20	Add new article codes 4515501N-01, 4513800N-01, 4513801N-01
19	Add new article codes 4637110, 4637120, 4638110, 4638120

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:

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