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

Espocan®
Espocan® NRFit®
Katheter-Sets zur Spinal-Epidural-Anästhesie (CSE)

Catheter sets for spinal/epidural anaesthesia (CSE)

Perifix®,
Perifix® Complete Set (LOR) with Soft Tip Catheter,
Perifix® NRFit®
Perifix® ONE,
Perifix® ONE Complete Set (LOR),
Perifix® ONE NRFit®,
Perifix® ONE Paed,
Perifix® ONE Paed NRFit®
Perifix® Soft Tip,
Perifix® Soft Tip NRFit®
Set zur kontinuierlichen Epiduralanästhesie

Set for continuous epidural anaesthesia

Perifix® Catheter,
Perifix Catheter NRFit®,
Perifix®-Katheter,
Perifix® ONE Catheter,
Perifix® ONE Catheter NRFit®
Perifix® Soft Tip Catheter,
Perifix Soft Tip Catheter NRFit®
Katheter zur Epiduralanästhesie

Catheters for epidural anaesthesia

(Artikelnummern siehe Anlage I)

(article numbers see attachment I)

Effective

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 der oben genannten Richtlinie	**Conformity Assessment Procedure** according to annex II of the Council Directive named above
Klassifizierung gemäß Anhang IX der oben genannten Richtlinie Klasse III	**Classification** according to annex IX of the Council Directive named above Class III
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 1997-01	**Date of first CE-marking** 1997-01
Gültig bis 2024-05-26	**Valid until** 2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4510097	Perifix® Soft Tip	III
4510097N-01	Perifix® Soft Tip NRFit®	III
4510216	Perifix® Soft Tip	III
4510291	Perifix® Soft Tip	III
4510305	Perifix® Soft Tip	III
4510305N-01	Perifix® NRFit®	III
4511000	Perifix®	III
4512006C	Perifix® ONE Paed	III
45120061N-01	Perifix® ONE Paed NRFit®	III
4512014C	Perifix® ONE Paed	III
45120141N-01	Perifix® ONE Paed NRFit®	III
4513002	Perifix®	III
4513002N-01	Perifix® NRFit®	III
4513010	Perifix®	III
4513029	Perifix®	III
4513100	Perifix®	III
4513150	Perifix® Catheter	III
4513150C	Perifix® ONE Catheter	III
4513150N-01	Perifix® Catheter NRFit®	III
45131501N-01	Perifix® ONE Catheter NRFit®	III
4513177	Perifix® Catheter	III
4513177N-01	Perifix® Catheter NRFit®	III
4513258	Perifix® Catheter	III
4513258C	Perifix® ONE Catheter	III
4513258N-01	Perifix® Catheter NRFit®	III
45132581N-01	Perifix® ONE Catheter NRFit®	III
4514009	Perifix®	III
4514009C	Perifix® ONE	III
4514009N-01	Perifix® NRFit®	III
4514017	Perifix®	III
4514017C	Perifix® ONE	III
45140171N-01	Perifix® ONE NRFit®	III
4514017N-01	Perifix ® NRFit®	III
4514025	Perifix®	III
4514025C	Perifix® ONE	III
45140251N-01	Perifix® ONE NRFit®	III
4514025N-01	Perifix® NRFit®	III

Effective

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4514183C	Perifix® ONE	III
4514203	Perifix®	III
4514203C	Perifix® ONE	III
4514211	Perifix®	III
4514211C	Perifix® ONE	III
4514211N-01	Perifix® NRFit®	III
45142111N-01	Perifix® ONE NRFit®	III
4514300	Perifix®	III
4514319	Perifix®	III
4514319C	Perifix® ONE	III
4514513	Perifix®	III
4514513C	Perifix® ONE	III
4515048	Perifix® Soft Tip Catheter	III
4515048N-01	Perifix® Soft Tip Catheter NRFit®	III
4516206	Perifix®	III
4517309	Perifix® Soft Tip	III
4517309N-01	Perifix® Soft Tip NRFit®	III
4517504	Perifix® Soft Tip	III
4556666	Espocan®	III
4556666N-01	Espocan® NRFit®	III
4556674	Espocan®	III
4556674N-01	Espocan® NRFit®	III
4556747	Espocan®	III
4556747N-01	Espocan® NRFit®	III
4556763	Espocan®	III
4556763N-01	Espocan® NRFit®	III

Effective

Amendment Information

Version	Description of the changes
26	Add new article code 4556666N-01, 4556674N-01, 4556747N-01, 4556763N-01 Delete “out of market” article codes 4512006CS, 4512014CS, 4514017CS, 4514017S, 4514025CS, 4514025S, 4514050CS, 4514319S, 4516206S, 4517309S Article codes 4050114, 4050115, 4056841, 4454911, 4459180 discontinued in the context of certificate extension Change product name of article codes 4513150, 4513177 from Perifix-Katheter to Perifix Catheter
25	Add new article code 4459180, delete “out of market” article codes 4512006, 4512260, 4513002C, 4513010C, 4513029C, 4513100C, 4513151, 4514050C, 4514300C
24	Delete “out of market” article code 4514050
23	Delete “out of market” article codes 4512014, 4515005, 4515013, 4515021, 4515200
22	Add new article codes 4510097N, 4510305N-01, 45120061N-01, 45120141N-01, 4513002N-01, 4513150N-01, 45131501N-01, 4513177N-01, 4513258N-01, 45132581N-01, 4514009N-01, 4514017N-01, 45140171N-01, 4514025N-01, 45140251N-01, 4514211N-01, 45142111N-01, 4515048N-01, 4517309N-01

Title: Declaration of Conformity - 39.05.157b - Espocan_Perifix 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, 05 May 2020, 13:06 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, 05 May 2020, 20:13 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Goebel, Udo (goebudde)
Title: HC-RA-DE08E Head of RA Pain Control & CVC
Date: Wednesday, 06 May 2020, 12:27 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective