

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 das die Produkte

Perican®, Perican® NRFit®
Perican® Paed, Perican® Paed NRFit®

Epiduralkanüle für die Single-Shot-Technik und
Epiduralkathetereinsatz

Basis UDI-DI 40392390000023912R
(Artikelnummern siehe Anlage I)

Epican® Paed, Epican® Paed NRFit®

Epiduralkanüle für die pädiatrische
Kaudalanästhesie (Single-Shot-Technik)

Basis UDI-DI 40392390000027953M
(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 III

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

hereby declare in our own responsibility
that the products

Perican®, Perican® NRFit®
Perican® Paed, Perican® Paed NRFit®

Epidural needle for Single Shot Technique and
Epidural Catheter Insertion

Basic UDI-DI 40392390000023912R
(article numbers see attachment I)

Epican® Paed, Epican® Paed NRFit®

Epidural needle for Pediatric Caudal Anesthesia
(Single Shot)

Basic UDI-DI 40392390000027953M
(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 III

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Gültig bis
gemäß gültigem EU Zertifikat
G12 012974 0651
G70 012974 0648

Valid until
according to our valid EC Certificate
G12 012974 0651
G70 012974 0648

Anlage I / Attachment I**Basic UDI-DI 40392390000023912R**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4512383	Perican®	III
4512200	Perican®	III
4512588	Perican®	III
4512782	Perican®	III
4512453	Perican®	III
4502078	Perican® Paed	III
4502094	Perican® Paed	III
4502302	Perican® Paed	III
4512383N-01	Perican® NRFit®	III
4512200N-01	Perican® NRFit®	III
4512782N-01	Perican® NRFit®	III
4512453N-01	Perican® NRFit®	III
4512785N-01	Perican® NRFit®	III
4512784N-01	Perican® NRFit®	III
4502078N-01	Perican® Paed NRFit®	III
4502094N-01	Perican® Paed NRFit®	III
4502302N-01	Perican® Paed NRFit®	III

Basic UDI-DI 40392390000027953M

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4502400	Epican® Paed	III
4502418	Epican® Paed	III
4502426	Epican® Paed	III
4502400N-01	Epican® Paed NRFit®	III
4502418N-01	Epican® Paed NRFit®	III
4502426N-01	Epican® Paed NRFit®	III

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR

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

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Effective