

**Konformitätserklärung
Declaration of Conformity**

Wir

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

We

erklären in eigener Verantwortung,
dass das/die Produkt/e**Epican® Paed,
Epican® Paed Caudal NRFit®,
Perican®, Perican® NRFit®, Perican®
Paed, Perican® Paed NRFit®**Kanülen zur Epidural-Anästhesie
(Artikelnummern siehe Anlage I)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse III**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123hereby declare in our own responsibility
that the product/s**Epican® Paed,
Epican® Paed Caudal NRFit®,
Perican®, Perican® NRFit®, Perican®
Paed, Perican® Paed NRFit®**Needles for epidural anaesthesia
(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
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class III**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Document No.: 39.05.157a

Version: 15.0

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Datum der ersten CE-Kennzeichnung

Epican® Paed	1998-12
Perican®, Perican® Paed	1997-01
Epican Paed NRFit®	2017-03
Perican NRFit®	2017-03
Perican Paed NRFit	2017-03

Gültig bis
2024-05-26**Date of first CE-marking**

Epican® Paed	1998-12
Perican®, Perican® Paed	1997-01
Epican Paed NRFit®	2017-03
Perican NRFit®	2017-03
Perican Paed NRFit	2017-03

Valid until
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4502078	Perican® Paed	III
4502078N-01	Perican® Paed NRFit®	III
4502094	Perican® Paed	III
4502094N-01	Perican® Paed NRFit®	III
4502302	Perican® Paed	III
4502302N-01	Perican® Paed NRFit®	III
4502400	Epican® Paed	III
4502400N-01	Epican® Paed Caudal NRFit®	III
4502418	Epican® Paed	III
4502418N-01	Epican® Paed Caudal NRFit®	III
4502426	Epican® Paed	III
4502426N-01	Epican® Paed Caudal NRFit®	III
4512200	Perican®	III
4512200N-01	Perican® NRFit®	III
4512383	Perican®	III
4512383N-01	Perican® NRFit®	III
4512453	Perican®	III
4512453N-01	Perican® NRFit®	III
4512588	Perican®	III
4512782	Perican®	III
4512782N-01	Perican® NRFit®	III
4512784N-01	Perican® NRFit®	III
4512785N-01	Perican® NRFit®	III

Amendment Information

Version	Description of the changes
15	Delete "out of market" article codes 4512200S, 4512384S, 4512453S, 4512782S, 4512783S, 4512784S, 4512785S
14	Delete "out of market" article code 4513908
13	Add new article codes 4502078N-01, 4502094N-01, 4502302N-01, 4502400N-01, 4502418N-01, 4502426N-01, 4512200N-01, 4512383N-01, 4512453N-01, 4512782N-01, 4512785N-01, 4512784N-01
12	Update TÜV address
11	General update

Title: Declaration of Conformity - 39.05.157a - Epidural needles 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
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UserName: Brand, Thomas (brantode)
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Meaning: Approve Document
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UserName: Goebel, Udo (goebudde)
Title: HC-RA-DE08E Head of RA Pain Control & CVC
Date: Wednesday, 06 May 2020, 12:26 W. Europe Daylight Time
Meaning: Approve Document
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Effective