

**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**Atraucan®,
Atraucan® Paed,
Führungskanüle,
Spinal Introducer ,
Pencan®,
Pencan® Paed,
Pencan® NRFit®,
Spinocan®,
Spinocan® NRFit®**Kanülen zur Spinal-Anästhesie
Kanüle für Spinal- und diagnostische Punktion

(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
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse III
Klasse IIahereby declare in our own responsibility
that the product/s**Atraucan®,
Atraucan® Paed,
Führungskanüle,
Spinal Introducer,
Pencan®,
Pencan® Paed,
Pencan® NRFit®,
Spinocan®,
Spinocan® NRFit®**Needles for Spinal Anaesthesia
Spinal Needle for spinal and diagnostic
puncture

(article numbers see attachment I)

is/are in compliance with the following
directiveCouncil Directive 93/42/EEC of 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II
according to annex II (excluding section 4)
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class III
Class IIa**Effective**

Document No.: 39.05.155a
Version: 30.0
Effective Date: 2021-10-07
Page: 2 of 8**Benannte Stelle**TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
1997-09**Gültig bis**
2024-05-26**Notified Body**TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
1997-09**Valid until**
2024-05-26

Anlage I / Attachment I

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 333877N-01 | Pencan® NRFit® | III |
| 4500059 | Führungskanüle | IIa |
| 4500059-13 | Spinal Introducer | IIa |
| 4501144 | Spinocan® | III |
| 4501144-13 | Spinocan® | III |
| 4501144N-01 | Spinocan® NRFit® | III |
| 4501195 | Spinocan® | III |
| 4501195-13 | Spinocan® | III |
| 4501195N-01 | Spinocan® NRFit® | III |
| 4501373 | Spinocan® | III |
| 4501373-13 | Spinocan® | III |
| 4501373N-01 | Spinocan® NRFit® | III |
| 4501390 | Spinocan® | III |
| 4501390-01 | Spinocan® | III |
| 4501390-10 | Spinocan® | III |
| 4501390N-01 | Spinocan® NRFit® | III |
| 4501900 | Spinocan® | III |
| 4501900-13 | Spinocan® | III |
| 4501900N-01 | Spinocan® NRFit® | III |
| 4501901N-01 | Spinocan® NRFit® | III |
| 4501918 | Spinocan® | III |
| 4501918-13 | Spinocan® | III |
| 4501918N-01 | Spinocan® NRFit® | III |
| 4502019 | Pencan® | III |
| 4502019-01 | Pencan® | III |
| 4502019-10 | Pencan® | III |
| 4502019N-01 | Pencan® NRFit® | III |
| 4502027 | Pencan® | III |
| 4502027-01 | Pencan® | III |
| 4502027-10 | Pencan® | III |
| 4502027N-01 | Pencan® NRFit® | III |
| 4502035 | Pencan® | III |
| 4502035-13 | Pencan® | III |
| 4502035N-01 | Pencan® NRFit® | III |
| 4502043 | Pencan® | III |
| 4502043-13 | Pencan® | III |
| 4502043N-01 | Pencan® NRFit® | III |

Effective

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 4502044N-01 | Pencan® NRFit® | III |
| 4502051 | Pencan® | III |
| 4502051-13 | Pencan® | III |
| 4502051N-01 | Pencan® NRFit® | III |
| 4502052N-01 | Pencan® NRFit® | III |
| 4502116 | Pencan® | III |
| 4502116-13 | Pencan® | III |
| 4502116N-01 | Pencan® NRFit® | III |
| 4502117N-01 | Pencan® NRFit® | III |
| 4502120-13 | Pencan® | III |
| 4502120N-01 | Pencan® NRFit® | III |
| 4502124 | Pencan® | III |
| 4502124-13 | Pencan® | III |
| 4502124N-01 | Pencan® NRFit® | III |
| 4502125N-01 | Pencan® NRFit® | III |
| 4502132 | Pencan® | III |
| 4502132-13 | Pencan® | III |
| 4502132N-01 | Pencan® NRFit® | III |
| 4502140 | Spinocan® | III |
| 4502140-13 | Spinocan® | III |
| 4502140N-01 | Spinocan® NRFit® | III |
| 4502159 | Pencan® Paed | III |
| 4502159-13 | Pencan® | III |
| 4502159N-01 | Pencan® NRFit® | III |
| 4502167 | Pencan® Paed | III |
| 4502167-13 | Pencan® | III |
| 4502167N-01 | Pencan® NRFit® | III |
| 4502175 | Pencan® Paed | III |
| 4502175N-01 | Pencan® NRFit® | III |
| 4502175-13 | Pencan® | III |
| 4502906 | Spinocan® | III |
| 4502906-01 | Spinocan® | III |
| 4502906-10 | Spinocan® | III |
| 4502906N-01 | Spinocan® NRFit® | III |
| 4503902 | Spinocan® | III |
| 4503902-01 | Spinocan® | III |
| 4503902-10 | Spinocan® | III |
| 4503902N-01 | Spinocan® NRFit® | III |
| 4504739 | Atraucan® | III |

Effective

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|----------------------------|-----------------------------------|-----------------------|
| 4504763 | Atraucan® Paed | III |
| 4504771 | Atraucan® Paed | III |
| 4504917 | Spinocan® | III |
| 4504917-13 | Spinocan® | III |
| 4504917N-01 | Spinocan® NRFit® | III |
| 4505000 | Führungskanüle | IIa |
| 4505000-13 | Spinal Introducer | IIa |
| 4505045 | Spinal Introducer | IIa |
| 4505751 | Spinocan® | III |
| 4505751-01 | Spinocan® | III |
| 4505751-10 | Spinocan® | III |
| 4505751N-01 | Spinocan® NRFit® | III |
| 4505905 | Spinocan® | III |
| 4505905-01 | Spinocan® | III |
| 4505905-10 | Spinocan® | III |
| 4505905N-01 | Spinocan® NRFit® | III |
| 4505913 | Spinocan® | III |
| 4505913-13 | Spinocan® | III |
| 4505913N-01 | Spinocan® NRFit® | III |
| 4506014-03 | Spinocan® | III |
| 4506090 | Spinocan® | III |
| 4506090-13 | Spinocan® | III |
| 4506090N-01 | Spinocan® NRFit® | III |
| 4506095N-01 | Spinocan® NRFit® | III |
| 4507401 | Spinocan® | III |
| 4507401-13 | Spinocan® | III |
| 4507401N-01 | Spinocan® NRFit® | III |
| 4507754 | Spinocan® | III |
| 4507754-13 | Spinocan® | III |
| 4507754N-01 | Spinocan® NRFit® | III |
| 4507908 | Spinocan® | III |
| 4507908-01 | Spinocan® | III |
| 4507908-10 | Spinocan® | III |
| 4507908N-01 | Spinocan® NRFit® | III |
| 4509757 | Spinocan® | III |
| 4509757-13 | Spinocan® | III |
| 4509757N-01 | Spinocan® NRFit® | III |
| 4509900 | Spinocan® | III |
| 4509900-01 | Spinocan® | III |

Effective

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|---------------------|----------------------------|----------------|
| 4509900-10 | Spinocan® | III |
| 4509900N-01 | Spinocan® NRFit® | III |

Amendment Information

| Version | Description of the changes |
|---------|---|
| 30 | Delete "out of market" article codes 4502248, 4502256 |
| 29 | Delete article codes 333877, 4506014 due to change HC-CHC-M-DIV-2228 Phase out for CE Market |
| 28 | Add article code 4505045 |
| 27 | Delete "out of market" article codes 333877-05, 4502183 |
| 26 | Delete "out of market" article codes 4502124S-13, 4502167S-13, 4506014S-13, 4501390S-01, 4502035S-13, 4502043S-13, 4502051S-13, 4502116S-13, 4502120S-13, 4502121S-13, 4502125S-13, 4502133S-13, 4502159S-13, 4505905S-01, 4507754S-13, 4509900S-13, 4507401S-13, 4506095S-13 |

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Title: Declaration of Conformity - 39.05.155a - Spinal needles 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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Date: Tuesday, 05 October 2021, 12:58 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Grosser, Simone (donnside)
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Date: Tuesday, 05 October 2021, 14:35 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Brand, Thomas (brantode)
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Date: Thursday, 07 October 2021, 11:59 W. Europe Daylight Time
Meaning: Approve Document
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