

**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® Pencil Point,
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
1993
über 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® Pencil Point,
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
1993
concerning 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: 28.0
Effective Date: 2020-04-08
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
333877	Pencan® Pencil Point	III
333877N-01	Pencan® NRFit®	III
4500059	Führungskanüle	Ila
4500059-13	Spinal Introducer	Ila
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

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Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4502043N-01	Pencan® NRFit®	III
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
4502248	Pencan®	III
4502256	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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4503902-10	Spinocan®	III
4503902N-01	Spinocan® NRFit®	III
4504739	Atraucan®	III
4504763	Atraucan® Paed	III
4504771	Atraucan® Paed	III
4504917	Spinocan®	III
4504917-13	Spinocan®	III
4504917N-01	Spinocan® NRFit®	III
4505000	Führungskanüle	Ila
4505000-13	Spinal Introducer	Ila
4505045	Spinal Introducer	Ila
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	Spinocan®	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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4509757-13	Spinocan®	III
4509757N-01	Spinocan® NRFit®	III
4509900	Spinocan®	III
4509900-01	Spinocan®	III
4509900-10	Spinocan®	III
4509900N-01	Spinocan® NRFit®	III

Amendment Information

Version	Description of the changes
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
25	Delete "out of market" article codes 4502141S-13, 4503903S-13, 4509757S-13
24	Delete „out of market“ article codes 4504739-13, 4504763-13, 4504771-13 Delete article code 4505042 because it's an ProSet and has to be allocated to 39.05.155aKIT

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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Meaning: Approve Document
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