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

Atraucan®,
Atraucan® Paed,
Führungskanüle,
Spinal Introducer ,
Pencan®,
Pencan® Paed,
Pencan® NRFit®,
Spinocan®,
Spinocan® NRFit®

Kanülen zur Spinal-Anästhesie
Kanüle für Spinal- und diagnostische Punktion

Needles for Spinal Anaesthesia
Spinal Needle for spinal and diagnostic puncture

(Artikelnummern siehe Anlage I)

(article numbers see attachment I)

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
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

Conformity Assessment Procedure
according to annex II
according to annex II (excluding section 4)
of the Council Directive named above

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse III
Klasse IIa

Classification
according to annex IX of the
Council Directive named above
Class III
Class IIa

Effective

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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

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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

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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

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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

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

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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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Meaning: Document signed as Author
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Date: Thursday, 07 October 2021, 11:59 W. Europe Daylight Time
Meaning: Approve Document
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