

**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 14<sup>th</sup> 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

Document No.: 39.05.155a

Version: 30.0

Effective Date: 2021-10-07

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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

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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
4506014-03	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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<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4509900-10	Spinocan®	III
4509900N-01	Spinocan® NRFit®	III

**Effective**

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
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

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:

UserName: Staufenberg, Sandra (stausade)  
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Date: Tuesday, 05 October 2021, 12:58 W. Europe Daylight Time  
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UserName: Grosser, Simone (donnside)  
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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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