

**Konformitätserklärung
Declaration of Conformity**

Wir

We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung,
dass die Produkte

Atraucan®
Pencan
Spinocan®

Spinalnadel für die intrathekale Injektionen und
diagnostische Lumbalpunktion

Basis UDI-DI: 40392390000008612T
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen

Konformitätsbewertungsverfahren
nach Anhang IX

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse III

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültigen EU Zertifikaten
G70 012974 0640
G12 012974 0651

hereby declare in our own responsibility
that the products

Atraucan®
Pencan
Spinocan®

Spinal Needle for Intrathecal Injections and
Diagnostic Lumbar Puncture

Basic UDI-DI: 40392390000008612T
(article numbers see attachment I)

are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to annex IX

Classification
according to annex VIII of the Regulation named
above
Class III

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until
according to our valid EU Certificates
G70 012974 0640
G12 012974 0651

Anlage I / Attachment I

Basic UDI-DI 40392390000008612T

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4521801	Spinocan®	III
4521801IN	Spinocan®	III
4521801N	Spinocan®	III
4522001	Spinocan®	III
4522001IN	Spinocan®	III
4522001N	Spinocan®	III
4522201	Spinocan®	III
4522201N	Spinocan®	III
4522202	Spinocan®	III
4522202N	Spinocan®	III
4522203	Spinocan®	III
4522203IN	Spinocan®	III
4522203N	Spinocan®	III
4522204	Spinocan®	III
4522204N	Spinocan®	III
4522301	Spinocan®	III
4522301IN	Spinocan®	III
4522301N	Spinocan®	III
4522501	Spinocan®	III
4522501N	Spinocan®	III
4522502	Spinocan®	III
4522502IN	Spinocan®	III
4522502N	Spinocan®	III
4522503	Spinocan®	III
4522503IN	Spinocan®	III
4522503N	Spinocan®	III
4522601	Spinocan®	III
4522601IN	Spinocan®	III
4522601N	Spinocan®	III
4522701	Spinocan®	III
4522701IN	Spinocan®	III
4522701N	Spinocan®	III
4522702	Spinocan®	III
4522702N	Spinocan®	III
4522703	Spinocan®	III
4522703N	Spinocan®	III
4522901	Spinocan®	III
4522901N	Spinocan®	III
4532201	Pencan	III
4532201N	Pencan	III
4532501	Pencan	III
4532501N	Pencan	III
4532502	Pencan	III
4532502N	Pencan	III

4532503	Pencan	III
4532503IN	Pencan	III
4532503N	Pencan	III
4532504	Pencan	III
4532504IN	Pencan	III
4532504N	Pencan	III
4532505	Pencan	III
4532505N	Pencan	III
4532506	Pencan	III
4532506N	Pencan	III
4532507	Pencan	III
4532507N	Pencan	III
4532508	Pencan	III
4532508N	Pencan	III
4532510	Pencan	III
4532510N	Pencan	III
4532701	Pencan	III
4532701N	Pencan	III
4532702	Pencan	III
4532702IN	Pencan	III
4532702N	Pencan	III
4532703	Pencan	III
4532703IN	Pencan	III
4532703N	Pencan	III
4532704	Pencan	III
4532704N	Pencan	III
4532705	Pencan	III
4532705N	Pencan	III
4532706	Pencan	III
4532706N	Pencan	III
4532707	Pencan	III
4532707N	Pencan	III
4542601	Atraucan®	III
4542602	Atraucan®	III
4542603	Atraucan®	III

Document amendment information

Version	Description of the changes
1.0	Initial version
2.0	Correction of article numbers 4532056N to 4532506N, 453707 to 4532707, 4542604 to 4542601 due to typing errors
3.0	- Addition of G70 012974 0640 Certificate - Deletion of NRFit® from product name
4.0	Correction of article numbers 4552202N to 4522202N and 4552204N to 4522204N due to typing errors

Title: Declaration of Conformity - 188-003-MDR - Spinal Needles ONE Hub Initiator: Nadine ? Knatz

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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