

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

hereby declare in our own responsibility
that the products

Pencan
Spinocan®

Spinalnadel für die spinal und diagnostische
Punktion

Pencan
Spinocan®

Spinal Needle for Spinal and Diagnostic
Puncture

Basis UDI-DI: 40392390000085938
(Artikelnummern siehe Anlage I)

Basic UDI-DI: 40392390000085938
(article numbers see attachment I)

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

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse III

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

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Gültig bis
gemäß gültigem EU Zertifikat
G12 012974 0651
G70 012974 0649

Valid until
according to our valid EU Certificate
G12 012974 0651
G70 012974 0649

Anlage I / Attachment I

Basic UDI-DI 403923900000085938

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4501144-13	Spinocan®	III
4501195-13	Spinocan®	III
4501373-13	Spinocan®	III
4501390-01	Spinocan®	III
4501390-10	Spinocan®	III
4501900-13	Spinocan®	III
4501918-13	Spinocan®	III
4502019-01	Pencan	III
4502019-10	Pencan	III
4502027-01	Pencan	III
4502027-10	Pencan	III
4502035-13	Pencan	III
4502043-13	Pencan	III
4502051-13	Pencan	III
4502116-13	Pencan	III
4502120-13	Pencan	III
4502124-13	Pencan	III
4502132-13	Pencan	III
4502140-13	Spinocan®	III
4502159-13	Pencan	III
4502167-13	Pencan	III
4502175-13	Pencan	III
4502906-01	Spinocan®	III
4502906-10	Spinocan®	III
4503902-01	Spinocan®	III
4503902-10	Spinocan®	III
4504917-13	Spinocan®	III
4505751-01	Spinocan®	III
4505751-10	Spinocan®	III
4505905-01	Spinocan®	III
4505905-10	Spinocan®	III
4505913-13	Spinocan®	III
4506014-03	Spinocan®	III
4506090-13	Spinocan®	III
4507401-13	Spinocan®	III
4507754-13	Spinocan®	III
4507908-01	Spinocan®	III
4507908-10	Spinocan®	III
4509757-13	Spinocan®	III
4509900-01	Spinocan®	III
4509900-10	Spinocan®	III

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR

Title: Declaration of Conformity - 188-005-MDR - Spinal Needles NHD Initiator: Nadine ? Knatz

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