# 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 das Produkt

**Spinal Introducer**
Führungskanüle für die Einführung einer Spinalnadeln

Basis UDI-DI: 403923900000085836
(Artikelnummern siehe Anlage I)

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

**Konformitätsbewertungsverfahren**
nach Anhang IX
der oben genannten Verordnung

**Klassifizierung**
gemäß Anhang VIII der oben genannten Verordnung
Klasse IIa

**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123

**Gültig bis**
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)

hereby declare in our own responsibility that the product

**Spinal Introducer**
Introducer needle used for introduction of a Spinal needle

Basic UDI-DI: 403923900000085836
(article numbers see attachment I)

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

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

**Classification**
according to annex VIII of the Regulation named above
Class IIa

**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123

**Valid until**
according to our valid EU Certificate
(No. G10 012974 0611)

Effective

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## Anlage I / Attachment I

**Basic UDI-DI 403923900000085836**

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|---|---|---|
| 4500059-13 | Spinal Introducer | IIa |
| 4505000-13 | Spinal Introducer | IIa |
| 4552001 | Spinal Introducer | IIa |
| 4552002 | Spinal Introducer | IIa |
| 4552003 | Spinal Introducer | IIa |
| 4552201 | Spinal Introducer | IIa |
| 4552202 | Spinal Introducer | IIa |
| 4552203 | Spinal Introducer | IIa |

Effective

**Document amendment information**

| Version | Description of the changes |
|---|---|
| 1.0 | Initial Version under 2017/745 MDR |
| 2.0 | Addition of Spinal Introducer (ONE Hub) articles 4552001, 4552002, 4552003, 4552201, 4552202, 4552203 |

Effective

Title: Declaration of Conformity - 188-004-MDR - Spinal Introducer Initiator: Mandy Doreen ? Kleinwechter

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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