

**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**Stimuplex® D
Stimuplex® D NRFit®**
Atraumatische Kanüle für periphere
NervenblockadenBasis UDI-DI: 40392390000008502N
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen**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
G10 012974 0611hereby declare in our own responsibility
that the products**Stimuplex® D
Stimuplex® D NRFit®**
Atraumatic needle for peripheral nerve blocksBasic UDI-DI: 40392390000008502N
(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
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
G10 012974 0611

Anlage I / Attachment I**Basic UDI-DI 4039239000008502N**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4892105	Stimuplex® D	Ila
4892105-23	Stimuplex® D	Ila
4892105CN	Stimuplex® D	Ila
4892105NR	Stimuplex® D NRFit®	Ila
4892108	Stimuplex® D	Ila
4892108-23	Stimuplex® D	Ila
4892108CN	Stimuplex® D	Ila
4892108NR	Stimuplex® D NRFit®	Ila
4892112	Stimuplex® D	Ila
4892112-23	Stimuplex® D	Ila
4892112CN	Stimuplex® D	Ila
4892112NR	Stimuplex® D NRFit®	Ila
4892115	Stimuplex® D	Ila
4892115-23	Stimuplex® D	Ila
4892115NR	Stimuplex® D NRFit®	Ila
4892134	Stimuplex® D	Ila
4892134-23	Stimuplex® D	Ila
4892134NR	Stimuplex® D NRFit®	Ila
4892137	Stimuplex® D	Ila
4892137-23	Stimuplex® D	Ila
4892137NR	Stimuplex® D NRFit®	Ila
4892153	Stimuplex® D	Ila
4892153-23	Stimuplex® D	Ila
4892153NR	Stimuplex® D NRFit®	Ila
4892155	Stimuplex® D	Ila
4892155-23	Stimuplex® D	Ila
4892155NR	Stimuplex® D NRFit®	Ila
4892205	Stimuplex® D	Ila
4892205-23	Stimuplex® D	Ila
4892205NR	Stimuplex® D NRFit®	Ila
4892208	Stimuplex® D	Ila
4892208-23	Stimuplex® D	Ila
4892208NR	Stimuplex® D NRFit®	Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR
2.0	Correction of article code 4892108-12 to 4892108-23

Title: Declaration of Conformity - 194-008-MDR - Stimuplex D Initiator: Stefan ? Wuttig

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

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Effective