

## 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® 360**  
**Stimuplex® Ultra 360**  
**Stimuplex® Ultra 360 NRFit®**  
Ultraschall-sichtbare Stimulationsnadel für  
periphere Nervenblockaden

Basis UDI-DI: 40392390000008512Q  
(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 0611

hereby declare in our own responsibility  
that the products

**Stimuplex® 360**  
**Stimuplex® Ultra 360**  
**Stimuplex® Ultra 360 NRFit®**  
Ultrasound-visible stimulation needle for  
peripheral nerve blocks

Basic UDI-DI: 40392390000008512Q  
(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 40392390000008512Q**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4892503-01	Stimuplex® Ultra 360	Ila
4892503-03	Stimuplex® Ultra 360	Ila
4892503-04	Stimuplex® Ultra 360	Ila
4892503-20	Stimuplex® Ultra 360	Ila
4892503CN	Stimuplex® 360	Ila
4892503NR-01	Stimuplex® Ultra 360 NRFit®	Ila
4892505-01	Stimuplex® Ultra 360	Ila
4892505-03	Stimuplex® Ultra 360	Ila
4892505-04	Stimuplex® Ultra 360	Ila
4892505-20	Stimuplex® Ultra 360	Ila
4892505CN	Stimuplex® 360	Ila
4892505NR-01	Stimuplex® Ultra 360 NRFit®	Ila
4892508-01	Stimuplex® Ultra 360	Ila
4892508-03	Stimuplex® Ultra 360	Ila
4892508-04	Stimuplex® Ultra 360	Ila
4892508-20	Stimuplex® Ultra 360	Ila
4892508CN	Stimuplex® 360	Ila
4892508NR-01	Stimuplex® Ultra 360 NRFit®	Ila
4892510-01	Stimuplex® Ultra 360	Ila
4892510-03	Stimuplex® Ultra 360	Ila
4892510-04	Stimuplex® Ultra 360	Ila
4892510-20	Stimuplex® Ultra 360	Ila
4892510CN	Stimuplex® 360	Ila
4892510NR-01	Stimuplex® Ultra 360 NRFit®	Ila
4892515-01	Stimuplex® Ultra 360	Ila
4892515-03	Stimuplex® Ultra 360	Ila
4892515-04	Stimuplex® Ultra 360	Ila
4892515-20	Stimuplex® Ultra 360	Ila
4892515-CN	Stimuplex® 360	Ila
4892515NR-01	Stimuplex® Ultra 360 NRFit®	Ila

**Effective**

**Document amendment information**

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR
2.0	Correction of product names for 4892510-20, 4892510NR-01 and 4892510CN

Title: Declaration of Conformity - 194-016-MDR - Stimuplex Ultra 360 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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