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

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Anlage I / Attachment I

Basic UDI-DI 40392390000008512Q

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

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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

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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:

UserName: Wuttig, Stefan (wuttstde)
Title: HC-RA-DE08 Senior Regulatory Affairs Manager
Date: Friday, 05 July 2024, 10:22 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Friday, 05 July 2024, 11:51 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Friday, 05 July 2024, 16:06 W. Europe Daylight Time
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