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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

Ultraplex® 360
Ultraplex® 360 NRFit®
Ultraschallsichtbare Stimulationskanüle für periphere Nervenblockaden

Ultraplex® 360
Ultraplex® 360 NRFit®
Ultrasound-visible stimulation needle for peripheral nerve blocks

Basis UDI-DI: 40392390000008552Y
(Artikelnummern siehe Anlage I)

Basic UDI-DI: 40392390000008552Y
(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 IIa

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

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
G10 012974 0611

Valid until
according to our valid EU Certificate
G10 012974 0611

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Anlage I / Attachment I

Basic UDI-DI 40392390000008552Y

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4892603-01	Ultraplex® 360	IIa
4892603CN	Ultraplex® 360	IIa
4892603NR-01	Ultraplex® 360 NRFit®	IIa
4892605-01	Ultraplex® 360	IIa
4892605CN	Ultraplex® 360	IIa
4892605NR-01	Ultraplex® 360 NRFit®	IIa
4892608-01	Ultraplex® 360	IIa
4892608CN	Ultraplex® 360	IIa
4892608NR-01	Ultraplex® 360 NRFit®	IIa
4892610-01	Ultraplex® 360	IIa
4892610CN	Ultraplex® 360	IIa
4892610NR-01	Ultraplex® 360 NRFit®	IIa
4892615-01	Ultraplex® 360	IIa
4892615CN	Ultraplex® 360	IIa
4892615NR-01	Ultraplex® 360 NRFit®	IIa

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Document amendment information

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

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Title: Declaration of Conformity - 194-017-MDR - Ultraplex 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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