

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

**Contiplex® S 360, Contiplex® S Ultra 360,
Contiplex® S Ultra 360 NRFit®
Contiplex® Tuohy Ultra 360, Contiplex®
Tuohy Ultra 360 NRFit®**

Kontinuierliches Katheterset für die periphere
Nervenblockade mit im Ultraschall sichtbaren
Stimulationsnadeln

Basis UDI-DI: 40392390000008542W
(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

**Contiplex® S 360, Contiplex® S Ultra 360,
Contiplex® S Ultra 360 NRFit®
Contiplex® Tuohy Ultra 360, Contiplex®
Tuohy Ultra 360 NRFit®**

Continuous peripheral nerve block catheter set
with ultrasound-visible stimulation needles

Basic UDI-DI: 40392390000008542W
(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 4039239000008542W**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4898650CN	Contiplex® S 360	Ila
4898650-01	Contiplex® S Ultra 360	Ila
4898650-27	Contiplex® S Ultra 360	Ila
4898650NR-27	Contiplex® S Ultra 360 NRFit®	Ila
4898610CN	Contiplex® S 360	Ila
4898610-01	Contiplex® S Ultra 360	Ila
4898610-27	Contiplex® S Ultra 360	Ila
4898610NR-27	Contiplex® S Ultra 360 NRFit®	Ila
4898615CN	Contiplex® S 360	Ila
4898615-01	Contiplex® S Ultra 360	Ila
4898615-27	Contiplex® S Ultra 360	Ila
4898615NR-27	Contiplex® S Ultra 360 NRFit®	Ila
4898704-01	Contiplex® Tuohy Ultra 360	Ila
4898704-27	Contiplex® Tuohy Ultra 360	Ila
4898704NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila
4898705-01	Contiplex® Tuohy Ultra 360	Ila
4898705-27	Contiplex® Tuohy Ultra 360	Ila
4898705NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila
4898710-01	Contiplex® Tuohy Ultra 360	Ila
4898710-27	Contiplex® Tuohy Ultra 360	Ila
4898710NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila
4898715-01	Contiplex® Tuohy Ultra 360	Ila
4898715-27	Contiplex® Tuohy Ultra 360	Ila
4898715NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR
2.0	Redactional update of the product name Contiplex® Tuohy Ultra 360. The word "Ultra" has been added, as it was missing.

Title: Declaration of Conformity - 194-004-MDR - Contiplex Tuohy,S Initiator: Andreea ? Schade

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

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