

**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**Ultraplex® 360  
Ultraplex® 360 NRFit®**  
Ultraschallsichtbare Stimulationskanüle für  
periphere NervenblockadenBasis UDI-DI: 40392390000008552Y  
(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**Ultraplex® 360  
Ultraplex® 360 NRFit®**  
Ultrasound-visible stimulation needle for  
peripheral nerve blocksBasic UDI-DI: 40392390000008552Y  
(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 4039239000008552Y**

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

**Document amendment information**

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

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:

UserName: Wuttig, Stefan (wuttstde)  
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Meaning: Document signed as Author

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UserName: Seidel, Stefan (seidstde)  
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Meaning: Approve Document

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