

## Konformitätserklärung Declaration of Conformity

Wir

We

**B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Deutschland/Germany**

erklären in eigener Verantwortung,  
dass das/die Produkt/e

hereby declare in our own responsibility  
that the product/s

**Contiplex® C, Contiplex® C NRFit®,  
Contiplex® D, Contiplex® D Set,  
Contiplex® D NRFit®, Contiplex® S,  
Contiplex® S NRFit®, Contiplex® S Ultra,  
Contiplex® S 360, Contiplex® S Ultra 360,  
Contiplex® S Ultra 360 NRFit®,  
Contiplex® Tuohy, Contiplex® Tuohy NRFit®,  
Contiplex® Tuohy Ultra,  
Contiplex® Tuohy Ultra 360,  
Contiplex® Tuohy Ultra 360 NRFit®,**

**Contiplex® C, Contiplex® C NRFit®,  
Contiplex® D, Contiplex® D Set,  
Contiplex® D NRFit®, Contiplex® S,  
Contiplex® S NRFit®, Contiplex® S Ultra,  
Contiplex® S 360, Contiplex® S Ultra 360,  
Contiplex® S Ultra 360 NRFit®,  
Contiplex® Tuohy, Contiplex® Tuohy  
NRFit®, Contiplex® Tuohy Ultra,  
Contiplex® Tuohy Ultra 360,  
Contiplex® Tuohy Ultra 360 NRFit®,**

**Stimuplex® A, Stimuplex® A NRFit®,  
Stimuplex® Ultra, Stimuplex® 360,  
Stimuplex® Ultra 360®, Stimuplex® D,  
Stimuplex® D NRFit®, Stimuplex® D Plus,  
Stimuplex® D Ultra,  
Stimuplex® Ultra 360® NRFit®,  
Ultraplex®, Ultraplex® 360,  
Ultraplex® 360 NRFit®**

**Stimuplex® A, Stimuplex® A NRFit®,  
Stimuplex® Ultra, Stimuplex® 360,  
Stimuplex® Ultra 360®, Stimuplex® D,  
Stimuplex® D NRFit®, Stimuplex® D Plus,  
Stimuplex® D Ultra,  
Stimuplex® Ultra 360® NRFit®,  
Ultraplex®, Ultraplex® 360,  
Ultraplex® 360 NRFit®**

Kanülen und Kathetersets zur Plexusanästhesie  
(Artikelnummern siehe Anlage I)

Needles and Catheterkits for Plexus  
Anaesthesia  
(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie  
übereinstimmt/übereinstimmen

is/are in compliance with the following  
directive

Richtlinie 93/42/EWG des Rates vom 14. Juni  
1993  
über Medizinprodukte  
geändert durch Richtlinie 2007/47/EG

Council Directive 93/42/EEC of 14<sup>th</sup> June  
1993  
concerning Medical Devices  
amended by Directive 2007/47/EC

**Konformitätsbewertungsverfahren**  
nach Anhang II (ausgenommen Abschnitt 4)  
der oben genannten Richtlinie

**Conformity Assessment Procedure**  
according to annex II (excluding section 4)  
of the Council Directive named above

**Effective**

**Klassifizierung**  
gemäß Anhang IX der  
oben genannten Richtlinie  
Klasse IIa

**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123

**Datum der ersten CE-Kennzeichnung**

Stimuplex® A  
1994-12

Contiplex® D  
Contiplex® D Set  
Stimuplex® D  
1998-12

Contiplex® Tuohy  
2000-12

Contiplex® S  
2008-12

Stimuplex® D Plus  
2009-12

Contiplex® C  
Contiplex® S Ultra  
Contiplex® Tuohy Ultra  
Stimuplex® Ultra  
Ultraplex®  
2011-12

Stimuplex® Ultra 360®  
2015-05

Ultraplex® 360  
2015-07

Contiplex® S Ultra 360  
Contiplex® Tuohy Ultra 360  
2016-08

**Classification**  
according to annex IX of the  
Council Directive named above  
Class IIa

**Notified Body**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123

**Date of first CE-marking**

Stimuplex® A  
1994-12

Contiplex® D  
Contiplex® D Set  
Stimuplex® D  
1998-12

Contiplex® Tuohy  
2000-12

Contiplex® S  
2008-12

Stimuplex® D Plus  
2009-12

Contiplex® C  
Contiplex® S Ultra  
Contiplex® Tuohy Ultra  
Stimuplex® Ultra  
Ultraplex®  
2011-12

Stimuplex® Ultra 360®  
2015-05

Ultraplex® 360  
2015-07

Contiplex® S Ultra 360  
Contiplex® Tuohy Ultra 360  
2016-08

Stimuplex® Ultra 360® NRFit®  
2017-07

Stimuplex A NRFit®  
Ultraplex® 360 NRFit®  
2017-10

Contiplex® D NRFit®  
Contiplex® S NRFit®  
Contiplex® S Ultra 360 NRFit®  
Contiplex® Tuohy NRFit®  
Contiplex® Tuohy Ultra 360 NRFit®  
2018-01

Contiplex® S 360  
Stimuplex® 360  
2018-02

Contiplex C NRFit®  
2018-05

Stimuplex D NRFit®  
2019-09

**Gültig bis**  
2024-05-26

Stimuplex® Ultra 360® NRFit®  
2017-07

Stimuplex A NRFit®  
Ultraplex® 360 NRFit®  
2017-10

Contiplex® D NRFit®  
Contiplex® S NRFit®  
Contiplex® S Ultra 360 NRFit®  
Contiplex® Tuohy NRFit®  
Contiplex® Tuohy Ultra 360 NRFit®  
2018-01

Contiplex® S 360  
Stimuplex® 360  
2018-02

Contiplex C NRFit®  
2018-05

Stimuplex D NRFit®  
2019-09

**Valid until**  
2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
331691N	Contiplex® Tuohy	Ila
331691NC	Contiplex® Tuohy Ultra	Ila
331693N	Contiplex® Tuohy	Ila
331693NC	Contiplex® Tuohy Ultra	Ila
331694N	Contiplex® Tuohy	Ila
331694NC	Contiplex® Tuohy Ultra	Ila
331695N	Contiplex® Tuohy	Ila
331695NC	Contiplex® Tuohy Ultra	Ila
4892105	Stimuplex® D	Ila
4892105-23	Stimuplex® D	Ila
4892105CN	Stimuplex® D	Ila
4892105NR	Stimuplex® D NRFit®	Ila
4892108	Stimuplex® D	Ila
4892108-23	Stimuplex® D	Ila
4892108CN	Stimuplex® D	Ila
4892108NR	Stimuplex® D NRFit®	Ila
4892112	Stimuplex® D	Ila
4892112-23	Stimuplex® D	Ila
4892112CN	Stimuplex® D	Ila
4892112NR	Stimuplex® D NRFit®	Ila
4892115	Stimuplex® D	Ila
4892115-23	Stimuplex® D	Ila
4892115NR	Stimuplex® D NRFit®	Ila
4892134	Stimuplex® D	Ila
4892134-23	Stimuplex® D	Ila
4892134NR	Stimuplex® D NRFit®	Ila
4892137	Stimuplex® D	Ila
4892137-23	Stimuplex® D	Ila
4892137NR	Stimuplex® D NRFit®	Ila
4892153	Stimuplex® D	Ila
4892153-23	Stimuplex® D	Ila
4892153NR	Stimuplex® D NRFit®	Ila
4892155	Stimuplex® D	Ila
4892155-23	Stimuplex® D	Ila
4892155NR	Stimuplex® D NRFit®	Ila
4892204	Stimuplex® D	Ila
4892204-23	Stimuplex® D	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4892204NR	Stimuplex® D NRFit®	Ila
4892205	Stimuplex® D	Ila
4892205-23	Stimuplex® D	Ila
4892205CN	Stimuplex® D	Ila
4892205NR	Stimuplex® D NRFit®	Ila
4892208	Stimuplex® D	Ila
4892208-23	Stimuplex® D	Ila
4892208CN	Stimuplex® D	Ila
4892208NR	Stimuplex® D NRFit®	Ila
4892303	Stimuplex® D Ultra	Ila
4892308	Stimuplex® D Ultra	Ila
4892312	Stimuplex® D Ultra	Ila
4892350	Stimuplex® D Ultra	Ila
4892402N	Contiplex® D Set	Ila
4892405	Stimuplex® D Ultra	Ila
4892410N	Contiplex® D Set	Ila
4892503	Stimuplex® Ultra	Ila
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	Stimuplex® Ultra	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	Stimuplex® Ultra	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	Stimuplex® Ultra	Ila
4892510-01	Stimuplex® Ultra 360®	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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	Stimuplex® Ultra	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
4892515CN	Stimuplex® 360	IIa
4892515NR-01	Stimuplex® Ultra 360® NRFit®	IIa
4892603	Ultraplex®	IIa
4892603-01	Ultraplex® 360	IIa
4892603-03	Ultraplex® 360	IIa
4892603-04	Ultraplex® 360	IIa
4892603-20	Ultraplex® 360	IIa
4892603CN	Ultraplex® 360	IIa
4892603NR-01	Ultraplex® 360 NRFit®	IIa
4892605	Ultraplex®	IIa
4892605-01	Ultraplex® 360	IIa
4892605-03	Ultraplex® 360	IIa
4892605-04	Ultraplex® 360	IIa
4892605-20	Ultraplex® 360	IIa
4892605CN	Ultraplex® 360	IIa
4892605NR-01	Ultraplex® 360 NRFit®	IIa
4892608	Ultraplex®	IIa
4892608-01	Ultraplex® 360	IIa
4892608-03	Ultraplex® 360	IIa
4892608-04	Ultraplex® 360	IIa
4892608-20	Ultraplex® 360	IIa
4892608CN	Ultraplex® 360	IIa
4892608NR-01	Ultraplex® 360 NRFit®	IIa
4892610	Ultraplex®	IIa
4892610-01	Ultraplex® 360	IIa
4892610-03	Ultraplex® 360	IIa
4892610-04	Ultraplex® 360	IIa
4892610-20	Ultraplex® 360	IIa
4892610CN	Ultraplex® 360	IIa

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4892610NR-01	Ultraplex® 360 NRFit®	IIa
4892615	Ultraplex®	IIa
4892615-01	Ultraplex® 360	IIa
4892615-03	Ultraplex® 360	IIa
4892615-04	Ultraplex® 360	IIa
4892615-20	Ultraplex® 360	IIa
4892615CN	Ultraplex® 360	IIa
4892615NR-01	Ultraplex® 360 NRFit®	IIa
4894001U	Ultraplex®	IIa
4894002U	Ultraplex®	IIa
4894003U	Ultraplex®	IIa
4894004U	Ultraplex®	IIa
4894005U	Ultraplex®	IIa
4894103N	Stimuplex® D	IIa
4894103U	Stimuplex® D Plus	IIa
4894111N	Stimuplex® D	IIa
4894120N	Stimuplex® D	IIa
4894138N	Stimuplex® D	IIa
4894146N	Stimuplex® D	IIa
4894146U	Stimuplex® D Plus	IIa
4894154N	Stimuplex® D	IIa
4894154U	Stimuplex® D Plus	IIa
4894162	Stimuplex® D	IIa
4894162N	Stimuplex® D	IIa
4894162U	Stimuplex® D Plus	IIa
4894170N	Stimuplex® D	IIa
4894189N	Stimuplex® D	IIa
4894197N	Stimuplex® D	IIa
4894197U	Stimuplex® D Plus	IIa
4894200N	Stimuplex® D	IIa
4894219N	Contiplex® D	IIa
4894227N	Contiplex® D	IIa
4894235N	Contiplex® D Set	IIa
4894235NCN	Contiplex® D Set	IIa
4894243N	Contiplex® D Set	IIa
4894243NC	Contiplex® D Set	IIa
4894243NCN	Contiplex® D Set	IIa
4894251	Stimuplex® A	IIa
4894251NR	Stimuplex® A NRFit®	IIa

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4894251NR-02	Stimuplex® A NRFit®	IIa
4894260	Stimuplex® A	IIa
4894260NR	Stimuplex® A NRFit®	IIa
4894260NR-02	Stimuplex® A NRFit®	IIa
4894260U	Stimuplex® Ultra	IIa
4894278	Stimuplex® A	IIa
4894278NR	Stimuplex® A NRFit®	IIa
4894278NR-02	Stimuplex® A NRFit®	IIa
4894278U	Stimuplex® Ultra	IIa
4894279U	Stimuplex® Ultra	IIa
4894294N	Contiplex® D	IIa
4894367	Stimuplex® A	IIa
4894367NR	Stimuplex® A NRFit®	IIa
4894367NR-02	Stimuplex® A NRFit®	IIa
4894367U	Stimuplex® Ultra	IIa
4894375	Stimuplex® A	IIa
4894375NR	Stimuplex® A NRFit®	IIa
4894375NR-02	Stimuplex® A NRFit®	IIa
4894391N	Contiplex® D Set	IIa
4894391NCN	Contiplex® D Set	IIa
4894502	Stimuplex® A	IIa
4894502NR	Stimuplex® A NRFit®	IIa
4894502NR-02	Stimuplex® A NRFit®	IIa
4894502U	Stimuplex® Ultra	IIa
4894539	Stimuplex® A	IIa
4894539NR	Stimuplex® A NRFit®	IIa
4894539NR-02	Stimuplex® A NRFit®	IIa
4895000	Contiplex® C	IIa
4895819N	Contiplex® D Set	IIa
4895819NCN	Contiplex® D Set	IIa
4898115	Contiplex® C	IIa
4898115NR	Contiplex® C NRFit®	IIa
4898130	Contiplex® C	IIa
4898130NR	Contiplex® C NRFit®	IIa
4898205	Contiplex® D	IIa
4898211	Contiplex® D	IIa
4898235	Contiplex® D	IIa
4898305	Contiplex® D Set	IIa
4898305NR	Contiplex® D NRFit®	IIa



<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4898308	Contiplex® D Set	Ila
4898311	Contiplex® D Set	Ila
4898311NR	Contiplex® D NRFit®	Ila
4898323	Contiplex® D Set	Ila
4898323NR	Contiplex® D NRFit®	Ila
4898325	Contiplex® D Set	Ila
4898325NR	Contiplex® D NRFit®	Ila
4898335	Contiplex® D Set	Ila
4898335NR	Contiplex® D NRFit®	Ila
4898405	Contiplex® S	Ila
4898405NR	Contiplex® S NRFit®	Ila
4898410	Contiplex® S	Ila
4898410NR	Contiplex® S NRFit®	Ila
4898415	Contiplex® S	Ila
4898415NR	Contiplex® S NRFit®	Ila
4898504	Contiplex® Tuohy	Ila
4898504NR	Contiplex® Tuohy NRFit®	Ila
4898505	Contiplex® Tuohy	Ila
4898505NR	Contiplex® Tuohy NRFit®	Ila
4898510	Contiplex® Tuohy	Ila
4898510NR	Contiplex® Tuohy NRFit®	Ila
4898515	Contiplex® Tuohy	Ila
4898515NR	Contiplex® Tuohy NRFit®	Ila
4898610	Contiplex® S Ultra	Ila
4898610-01	Contiplex® S Ultra 360	Ila
4898610-27	Contiplex® S Ultra 360	Ila
4898610CN	Contiplex® S 360	Ila
4898610NR-27	Contiplex® S Ultra 360 NRFit®	Ila
4898615	Contiplex® S Ultra	Ila
4898615-01	Contiplex® S Ultra 360	Ila
4898615-27	Contiplex® S Ultra 360	Ila
4898615CN	Contiplex® S 360	Ila
4898615NR-27	Contiplex® S Ultra 360 NRFit®	Ila
4898650	Contiplex® S Ultra	Ila
4898650-01	Contiplex® S Ultra 360	Ila
4898650-27	Contiplex® S Ultra 360	Ila
4898650CN	Contiplex® S 360	Ila
4898650NR-27	Contiplex® S Ultra 360 NRFit®	Ila
4898704	Contiplex® Tuohy Ultra	Ila

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4898704-01	Contiplex® Tuohy Ultra 360	Ila
4898704-27	Contiplex® Tuohy Ultra 360	Ila
4898704NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila
4898705	Contiplex® Tuohy Ultra	Ila
4898705-01	Contiplex® Tuohy Ultra 360	Ila
4898705-27	Contiplex® Tuohy Ultra 360	Ila
4898705NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila
4898710	Contiplex® Tuohy Ultra	Ila
4898710-01	Contiplex® Tuohy Ultra 360	Ila
4898710-27	Contiplex® Tuohy Ultra 360	Ila
4898710NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila
4898715	Contiplex® Tuohy Ultra	Ila
4898715-01	Contiplex® Tuohy Ultra 360	Ila
4898715-27	Contiplex® Tuohy Ultra 360	Ila
4898715NR-01	Contiplex® Tuohy Ultra 360 NRFit®	Ila
4898750	Contiplex® S	Ila
4898750NC	Contiplex® S Ultra	Ila
4898752	Contiplex® S	Ila
4898752NC	Contiplex® S Ultra	Ila
4898754	Contiplex® S	Ila
4898754NC	Contiplex® S Ultra	Ila

### Amendment Information

Version	Description of the changes
54	Delete "out of market" articles 4892402NC, 4892410NC, 4895001, 4895819NC
53	Delete "out of market" article codes 4894103, 4894120, 4894138, 4894146, 4894154, 4894170, 4894189, 4894200, 4894219, 4894235, 4894243, 4894391
52	Add new article codes 4892150NR, 4892108NR, 4892112NR, 4892115NR, 4892134NR, 4892137NR, 4892153NR, 4892155NR, 4892204NR, 4892205NR, 4892208NR
51	Add new article codes 4894251NR-02, 4894260NR-02, 4894278NR-02, 4894367NR-02, 4894375NR-02, 4894502NR-02, 4894539NR-02
50	Delete article codes 4898704NR-27, 4898705NR-27, 4898710NR-27, 4898715NR-27 because they will not implemented

Title: Declaration of Conformity - 39.05.153 - PNB Initiator: Sandra ? Staufenberg

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

UserName: Staufenberg, Sandra (stausade)  
Title: Administrator Regulatory Affairs CoE Pain Control & CVC  
Date: Thursday, 23 April 2020, 12:57 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Thursday, 23 April 2020, 22:02 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Goebel, Udo (goebudde)  
Title: HC-RA-DE08E Head of RA Pain Control & CVC  
Date: Friday, 24 April 2020, 06:55 W. Europe Daylight Time  
Meaning: Approve Document  
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