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
Stimuplex® Onvision **Stimuplex® Onvision NRFit®** Stimulationsnadel für die periphere Nervenblockade für die Verwendung mit dem Philips Onvision System	**Stimuplex® Onvision** **Stimuplex® Onvision NRFit®** Stimulation needle for peripheral nerve blocks for use with Philips Onvision System
(Artikelnummern siehe Anlage I)	(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 14th 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
Klassifizierung gemäß Anhang IX der oben genannten Richtlinie Klasse IIa	**Classification** according to annex IX of the Council Directive named above Class IIa
Benannte Stelle TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Deutschland Kennnummer 0123	**Notified Body** TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany Identification number 0123
Datum der ersten CE-Kennzeichnung 2018-09	**Date of first CE-marking** 2018-09

Effective

Gültig bis	**Valid until**
2024-05-26	2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. no.	Produktname / Product name	Klasse / Class
4892705-01	Stimuplex® Onvision	IIa
4892705NR-01	Stimuplex® Onvision NRFit®	IIa
4892708-01	Stimuplex® Onvision	IIa
4892708NR-01	Stimuplex® Onvision NRFit®	IIa
4892710-01	Stimuplex® Onvision	IIa
4892710NR-01	Stimuplex® Onvision NRFit®	IIa
4892712-01	Stimuplex® Onvision	IIa
4892712NR-01	Stimuplex® Onvision NRFit®	IIa
4892715-01	Stimuplex® Onvision	IIa
4892715NR-01	Stimuplex® Onvision NRFit®	IIa

Amendment Information

Version	Description of the changes
05	Delete article codes 4892705NR-02, 4892708NR-02, 4892710NR-02, 4892712NR-02, 4892715NR-02 due to adaption of portfolio
04	Add article codes 4892708-01, 4892712-01, 4892715-01, 4892705-02, 4892705NR-01, 4892708NR-01, 4892710NR-01, 4892712NR-01, 4892715NR-01, 4892705NR-02, 4892708NR-02, 4892710NR-02, 4892712NR-02, 4892715NR-02
03	Add art. No. 4892705-01
02	Delete Conformity Assessment Procedure annex VII and V
01	Initial version for art. no. 4892710-01

Title: Declaration of Conformity - 057-001 - Stimuplex Onvision Initiator: Sandra ? Staufenberg

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

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Date: Wednesday, 15 April 2020, 13:14 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Goebel, Udo (goebudde)
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UserName: Brand, Thomas (brantode)
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Date: Wednesday, 15 April 2020, 16:36 W. Europe Daylight Time
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