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

Stimuplex® Pen
Instrument zur kutanen elektrischen Nervenstimulation
(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmen

Konformitätsbewertungsverfahren
nach Artikel 52 Absatz 7 der oben genannten Verordnung

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I

Gültig bis 2024-10-21
gemäß gültigem ISO Zertifikat
Q5 012974 0590

hereby declare in our own responsibility that the products

Stimuplex® Pen
Device for cutaneous electrical nerve stimulation

(article numbers and Basic UDI-DI see attachment I)

are in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to article 52 section 7 of the Regulation named above

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

Valid until 2024-10-21
according to our valid ISO Certificate
Q5 012974 0590

Effective

Anlage I / Attachment I

Basic UDI-DI 4039239000000221ZE

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4892099	Stimuplex® Pen	I

Document amendment information

Version	Description of the changes
4.0	Addition of Certificate Number Q5 012974 0590
3.0	Adaption of Validity
2.0	Adaption of Validity
1.0	First issue of DoC acc. to MDR (HC-CHC-M-DIV-1776-Conversion of RMF 194-014 to MDR) replacing DoC acc. to MDD, document no.: 39.05.158CE, version 9.0

Title: Declaration of Conformity - 194-014-MDR - Stimuplex Pen Initiator: Sandra ? Staufenberg

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