

Radio Equipment Directive Compliance – EU Declaration of Conformity Vercise Genus™ DBS System and WaveWriter Alpha™ System

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Declaration of Conformity
Radio Equipment Directive (2014/53/EU)
English

Issuer's Name: Boston Scientific Neuromodulation Corporation
Issuer's Address: 25155 Rye Canyon Loop
Valencia, CA 91355
United States of America
Object of the declaration: Vercise Genus™ Deep Brain Stimulation System
WaveWriter Alpha™ System

Models addressed by this Declaration of Conformity are: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

The object of the declaration described above is in conformity with the relevant Union harmonized legislation and the following documents: Radio Equipment Directive (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Manufacturer

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
United States of America

EC Representative

Boston Scientific Limited
Ballybrit Business Park
Galway
Ireland

Boston Scientific Neuromodulation Corporation is exclusively responsible for the Declaration of Conformity.

Signed for and on behalf of: Boston Scientific Neuromodulation Corporation

Date of Issue:

DocuSigned by:



Signature: Rafael Carbunaru
Signing Reason: I approve this document
Signing Time: 19 October 2021 | 6:51:40 AM PDT
A5027EA413014C698C88320E44410619

Place of Issue: Valencia, CA

19 October 2021

Date of Signature

Declaración de conformidad
Directiva relativa a equipos radioeléctricos (2014/53/EU)
Español

Nombre del emisor: Boston Scientific Neuromodulation Corporation
Dirección del emisor: 25155 Rye Canyon Loop
Valencia, CA 91355
Estados Unidos de América
Objeto de la declaración: Sistema de estimulación cerebral profunda Vercise Genus™
Sistema WaveWriter Alpha™

Los modelos afectados por esta Declaración de conformidad son los siguientes: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

El objeto de la declaración anterior está en conformidad con la legislación armonizada correspondiente de la Unión Europea y con los documentos siguientes: Directiva relativa a equipos radioeléctricos (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Fabricante

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Estados Unidos de América

Representante en la UE

Boston Scientific Limited
Ballybrit Business Park
Galway
Irlanda

Boston Scientific Neuromodulation Corporation es exclusivamente responsable de la Declaración de conformidad.

Firmado en nombre de: Boston Scientific Neuromodulation Corporation

Fecha de publicación:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Vicepresidente de Investigación y Desarrollo
A5027EA413014C698C88320E44410619

Lugar de emisión: Valencia, CA

19 October 2021

Fecha de la firma

Déclaration de conformité
Directive européenne sur les équipements radio (2014/53/UE)
Français

Nom de l'émetteur : Boston Scientific Neuromodulation Corporation
Adresse de l'émetteur : 25155 Rye Canyon Loop
Valencia, CA 91355
États-Unis d'Amérique
Objet de la déclaration : Système de stimulation cérébrale profonde
(Deep Brain Stimulation, DBS) Vercise Genus™
Système WaveWriter Alpha™

Les modèles visés par la présente déclaration de conformité sont les suivants : DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R et SC-5572-1A.

L'objet de la déclaration décrite ci-dessus est conforme à la législation harmonisée pertinente de l'Union et aux documents suivants : Directive européenne sur les équipements radio (2014/53/UE).

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Fabricant

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
États-Unis d'Amérique

Représentant dans la CE

Boston Scientific Limited
Ballybrit Business Park
Galway
Irlande

Boston Scientific Neuromodulation Corporation est exclusivement responsable de la déclaration de conformité.

Signé au nom et pour le compte de : Boston Scientific Neuromodulation Corporation

Date de délivrance :

DocuSigned by:



Signature: Rafael Carburaru
Signing Reason: I approve this document
Vice-président, Recherche et développement
Signing Time: 19 October 2021 05:32 PM PDT
A5027EA413014C698C88320E44410619

Lieu de délivrance : Valencia, CA

19 October 2021

Date de la signature

Konformitätserklärung
Funkanlagenrichtlinie (2014/53/EU)
Deutsch

Name des Herausgebers: Boston Scientific Neuromodulation Corporation
Adresse des Herausgebers: 25155 Rye Canyon Loop
Valencia, CA 91355
USA
Gegenstand der Erklärung: Vercise Genus™ Deep Brain Stimulation System
WaveWriter Alpha™-System

Die in dieser Konformitätserklärung angesprochenen Modelle sind: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Der Gegenstand der oben beschriebenen Erklärung entspricht den relevanten harmonisierten Rechtsvorschriften der Union und den folgenden Dokumenten: Funkanlagenrichtlinie (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Hersteller	Bevollmächtigter in der Europäischen Gemeinschaft
Boston Scientific Neuromodulation Corporation	Boston Scientific Limited
25155 Rye Canyon Loop	Ballybrit Business Park
Valencia, CA 91355	Galway
USA	Irland

Die Boston Scientific Neuromodulation Corporation trägt die alleinige Verantwortung für die Konformitätserklärung.

Unterzeichnet für und im Namen von: Boston Scientific Neuromodulation Corporation

Ausgabedatum:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Leiter Forschung und Entwicklung
Signing Time: 19 October 2021 6:01:39 PM PDT
A5027EA413014C698C88320E44410619

Ausgabeort: Valencia, CA

19 October 2021

Datum der Unterschrift

Dichiarazione di conformità
Direttiva sulle apparecchiature radio (2014/53/UE)
Italiano

Nome del fornitore: Boston Scientific Neuromodulation Corporation
Indirizzo del fornitore: 25155 Rye Canyon Loop
Valencia, CA 91355
Stati Uniti d'America
Oggetto della dichiarazione: Sistema di stimolazione cerebrale profonda Vercise Genus™
Sistema WaveWriter Alpha™

I modelli interessati dalla presente Dichiarazione di conformità sono: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

L'oggetto della dichiarazione descritta sopra è conforme alla legislazione armonizzata in materia dell'Unione e ai seguenti documenti: Direttiva sulle apparecchiature radio (2014/53/UE).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Fabbricante

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Stati Uniti d'America

Rappresentante CE

Boston Scientific Limited
Ballybrit Business Park
Galway
Irlanda

Boston Scientific Neuromodulation Corporation è responsabile esclusivamente della Dichiarazione di Conformità.

Firmato per e per conto di: Boston Scientific Neuromodulation Corporation

Data di emissione:

DocuSigned by:


Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Vicepresidente, Ricerca e Sviluppo
Signing Time: 19 October 2021 16:09:45 PM PDT
A5027EA413014C698C88320E44410619

Luogo di emissione: Valencia, CA

19 October 2021

Data della firma

Verklaring van conformiteit
Richtlijn betreffende radioapparatuur (2014/53/EG)
Nederlands

Naam van de uitgever: Boston Scientific Neuromodulation Corporation
Adres van de uitgever: 25155 Rye Canyon Loop
Valencia, CA 91355
Verenigde Staten van Amerika
Onderwerp van de verklaring: Vercise Genus™-systeem voor diepe hersenstimulatie
WaveWriter Alpha™-systeem

De modellen behandeld door deze conformiteitsverklaring zijn: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Het onderwerp van de hierboven beschreven verklaring is conform de relevante geharmoniseerde wetgeving van de Gemeenschap en de volgende documenten: Richtlijn betreffende radioapparatuur (2014/53/EG).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Fabrikant

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Verenigde Staten van Amerika

Boston Scientific Neuromodulation Corporation is exclusief verantwoordelijk voor de Verklaring van conformiteit.

Vertegenwoordiger in de EU

Boston Scientific Limited
Ballybrit Business Park
Galway
Ierland

Ondertekend voor en namens: Boston Scientific Neuromodulation Corporation

Datum van uitgave:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document.
Vice-President, Onderzoek en ontwikkeling
Signing Time: 19 October 2021 16:01:55 PM PDT
A5027EA413014C698C88320E44410619

Plaats van uitgave: Valencia, CA

19 October 2021

Datum van ondertekening

**Försäkran om överensstämmelse med
direktiv om radioutrustning (2014/53/EU)**
Svenska

Utgivarens namn: Boston Scientific Neuromodulation Corporation
Utgivarens adress: 25155 Rye Canyon Loop
Valencia, CA 91355
USA
**Försäkran omfattar
följande system:** Vercise Genus™-systemet för djup hjärnstimulering
WaveWriter Alpha™-systemet

Modellerna som omfattas av den här försäkran är: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

System som listas ovan överensstämmer med relevant EU-lagstiftning och följande dokument: Direktiv om radioutrustning (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Tillverkare

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
USA

Ombud inom EU

Boston Scientific Limited
Ballybrit Business Park
Galway
Irland

Boston Scientific Neuromodulation Corporation är ensamt ansvariga för denna Försäkran om överensstämmelse.

Signerad av och för: Boston Scientific Neuromodulation Corporation

Utgivningsdatum:

DocuSigned by:



Signer Name: Rafael Carbunaru

Signing Reason: I approve this document

Vice President, Regulatory Affairs

Signing Time: 19 October 2021 15:57 PM PDT
A5027EA413014C698C88320E44410619

Utgivningsort: Valencia, CA

19 October 2021

Datum för undertecknande

Vaatimustenmukaisuusvakuutus
Radiolaitedirektiivi (2014/53/EU)
Finnish

Julkaisijan nimi: Boston Scientific Neuromodulation Corporation
Julkaisijan osoite: 25155 Rye Canyon Loop
Valencia, CA 91355
Yhdysvallat
Vakuutuksen kohde: Aivojen syvien osien Vercise Genus™ -stimulaatiojärjestelmä
WaveWriter Alpha™ -järjestelmä

Mallit, joita tämä vaatimustenmukaisuusvakuutus koskee, ovat seuraavat: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Yllä mainittu vakuutuksen kohde on unionin harmonisoidun lainsäädännön ja seuraavien asiakirjojen vaatimusten mukainen: Radiolaitedirektiivi (2014/53/EU).

EN 60601-1:2006 + A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Valmistaja

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Yhdysvallat

Edustaja Euroopan yhteisön alueella

Boston Scientific Limited
Ballybrit Business Park
Galway
Irlanti

Boston Scientific Neuromodulation Corporation on yksinomaisesti vastuussa vaatimustenmukaisuusvakuutuksesta.

Allekirjoitettu seuraavan tahon nimissä ja puolesta: Boston Scientific Neuromodulation Corporation

Julkaisupäivä:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Signed on: 19 October 2021 16:52:05 PM PDT
Apulainen, Jukka
A5027EA413014C698C88320E44410619

Julkaisupaikka: Valencia, CA

19 October 2021

Allekirjoituspäivä

Samsvarserklæring
Radiodirektivet (2014/53/EU)
Norsk

Utstederens navn: Boston Scientific Neuromodulation Corporation
Utstederens adresse: 25155 Rye Canyon Loop
Valencia, CA 91355
USA
Erklæringen gjelder: Vercise Genus™ System for dyp hjernestimulering
WaveWriter Alpha™-system

Modellene som er behandlet i denne erklæringen, er: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Denne erklæringen angir samsvar med relevant harmonisert lovgivning i EU og følgende dokumenter:
Radiodirektivet (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Produsent

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
USA

EC-representant

Boston Scientific Limited
Ballybrit Business Park
Galway
Irland

Boston Scientific Neuromodulation Corporation er eneansvarlig for samsvarserklæringen.

Signert for og på vegne av: Boston Scientific Neuromodulation Corporation

Utstedelsesdato:

DocuSigned by:



Signer Name: Rafael Carbunaru

Signing Reason: I approve this document

Signer's email address: rafael.carbunaru@boston-scientific.com

Signature ID: A5027EA413014C698C88320E44410619

Sted for utstedelse: Valencia, CA

19 October 2021

Signaturdato

Overensstemmelseserklæring
Radio Equipment Directive (Radioudstyrsdirektivet) (2014/53/EU)
Dansk

Udsteders navn: Boston Scientific Neuromodulation Corporation
Udsteders adresse: 25155 Rye Canyon Loop
Valencia, CA 91355
USA
Erklæringens formål: Vercise Genus™-system til dyb hjernestimulering
WaveWriter Alpha™-system

Modeller, som denne overensstemmelseserklæring omhandler, er: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Formålet med erklæringen beskrevet ovenfor er i overensstemmelse med den relevante lovgivning for fagområdet og følgende dokumenter: Radio Equipment Directive (Radioudstyrsdirektivet) (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Producent

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
USA

Repræsentant i EU

Boston Scientific Limited
Ballybrit Business Park
Galway
Irland

Boston Scientific Neuromodulation Corporation er eneansvarlig for overensstemmelseserklæringen.

Underskrevet for og på vegne af: Boston Scientific Neuromodulation Corporation

Udstedelsesdato

DocuSigned by:



Signer Name: Rafael Carbutaru
Signing Reason: I approve this document
Signing Time: 19 October 2021 16:21:18 PM PDT
A5027EA413014C698C88320E44410619

Udstedelsessted: Valencia, CA

19 oktober 2021

Underskrivelsesdato

Declaração de Conformidade
Diretiva de Equipamentos de Rádio (2014/53/UE)
Português

Nome do emissor: Boston Scientific Neuromodulation Corporation
Endereço do emissor: 25155 Rye Canyon Loop
Valencia, CA 91355
Estados Unidos da América
Objeto da declaração: Sistema de Estimulação Cerebral Profunda Vercise Genus™
Sistema WaveWriter Alpha™

Os modelos abordados por esta Declaração de Conformidade são os seguintes: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

O objeto da declaração acima descrita está em conformidade com a legislação harmonizada da União e com os seguintes documentos: Diretiva de Equipamentos de Rádio (2014/53/UE).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Fabricante

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Estados Unidos da América

Representante na CE

Boston Scientific Limited
Ballybrit Business Park
Galway
Irlanda

A Boston Scientific Neuromodulation Corporation é exclusivamente responsável pela Declaração de Conformidade.

Assinado por e em nome de: Boston Scientific Neuromodulation Corporation

Data de emissão:

DocuSigned by:



Signer Name: Rafael Carbunaru

Signing Reason: I approve this document

Vice-Presidente, Investigação e Desenvolvimento

A5027EA413014C698C88320E44410619

Local de emissão: Valencia, CA

19 October 2021

Data da assinatura

Δήλωση συμμόρφωσης
Οδηγία περί εξοπλισμού ραδιοσυχνοτήτων (2014/53/ΕΕ)
Ελληνικά

Όνομα εκδότη: Boston Scientific Neuromodulation Corporation
Διεύθυνση εκδότη: 25155 Rye Canyon Loop
Valencia, CA 91355
Ηνωμένες Πολιτείες Αμερικής
Αντικείμενο της δήλωσης: Το σύστημα εν τω βάθει εγκεφαλικής διέγερσης Vercise Genus™
Σύστημα WaveWriter Alpha™

Τα μοντέλα που καλύπτονται από αυτήν τη δήλωση συμμόρφωσης είναι: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Το αντικείμενο της δήλωσης που περιγράφεται παραπάνω είναι σύμφωνο προς τη σχετική ενωσιακή νομοθεσία εναρμόνισης και τα ακόλουθα έγγραφα: Οδηγία περί εξοπλισμού ραδιοσυχνοτήτων (2014/53/ΕΕ).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Κατασκευαστής

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Ηνωμένες Πολιτείες Αμερικής

Η παρούσα δήλωση συμμόρφωσης εκδίδεται με αποκλειστική ευθύνη της Boston Scientific Neuromodulation Corporation.

Αντιπρόσωπος ΕΚ

Boston Scientific Limited
Ballybrit Business Park
Galway
Ιρλανδία

Υπογραφή για λογαριασμό και εξ ονόματος: Boston Scientific Neuromodulation Corporation

Ημερομηνία έκδοσης:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Αντιπρόσωπος: Τηλεμόδορος για ανάπτυξης
A5027EA413014C698C88320E44410619

Τόπος έκδοσης: Valencia, CA

19 October 2021

Ημερομηνία υπογραφής

Prohlášení o shodě
Směrnice EU o radiových zařízeních (2014/53/EU)
Česky

Název vydavatele: Boston Scientific Neuromodulation Corporation
Adresa vydavatele: 25155 Rye Canyon Loop
Valencia, CA 91355
Spojené státy americké
Předmět prohlášení: Systém hluboké mozkové stimulace Vercise Genus™
Systém WaveWriter Alpha™

Modely řešené tímto prohlášením o shodě jsou: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Předmět shora uvedeného prohlášení je ve shodě s příslušnou harmonizovanou legislativou EU a následujícími dokumenty: Směrnice EU o radiových zařízeních (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Výrobce

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Spojené státy americké

Zástupce v ES

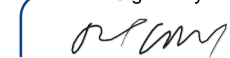
Boston Scientific Limited
Ballybrit Business Park
Galway
Irsko

Za prohlášení o shodě nese výhradní odpovědnost společnost Boston Scientific Neuromodulation Corporation.

Podepsáno za a jménem: Boston Scientific Neuromodulation Corporation

Datum vydání:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Místo podpisu: 19 October 2021 16:52:31 PM PDT
A5027EA413014C698C88320E44410619

Místo vydání: Valencia, CA

19 October 2021

Datum podpisu

Vyhlásenie o zhode
Smernica o rádiových zariadeniach (2014/53/EÚ)
Slovenčina

Názov vydavateľa: Boston Scientific Neuromodulation Corporation
Adresa vydavateľa: 25155 Rye Canyon Loop
Valencia, CA 91355
USA
Predmet vyhlásenia: Systém hĺbkovej mozgovej stimulácie Vercise Genus™
Systém WaveWriter Alpha™

Modely, ktorých sa týka toto vyhlásenie o zhode: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Predmet vyhlásenia uvedený vyššie je v zhode s príslušnou harmonizovanou legislatívou Európskej únie a s nasledujúcimi dokumentmi: Smernica o rádiových zariadeniach (2014/53/EÚ).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Výrobca

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
USA

Zástupca pre ES

Boston Scientific Limited
Ballybrit Business Park
Galway
Írsko

Spoločnosť Boston Scientific Neuromodulation Corporation je výlučne zodpovedná za toto Vyhlásenie o zhode.

Podpísané v mene: Boston Scientific Neuromodulation Corporation

Dátum vydania:

DocuSigned by:



Signer Name: Rafael Carbutaru
Signing Reason: I approve this document
Signed On: 19 October 2021 05:23:36 PM PDT
Signature ID: A5027EA413014C698C88320E44410619

Miesto vydania: Valencia, CA

19 October 2021

Dátum podpisu

Deklaracja zgodności
Dyrektywa w sprawie urządzeń radiowych (2014/53/UE)
Polski

Imię i nazwisko wydawcy: Boston Scientific Neuromodulation Corporation
Adres wydawcy: 25155 Rye Canyon Loop
Valencia, CA 91355
Stany Zjednoczone
Przedmiot zgodności: System głębokiej stymulacji mózgu Vercise Genus™
System WaveWriter Alpha™

Modele, których dotyczy niniejsza deklaracja zgodności: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Przedmiot deklaracji opisany powyżej jest zgodny z odpowiednimi zharmonizowanymi przepisami unijnymi oraz z następującymi dokumentami: Dyrektywa w sprawie urządzeń radiowych (2014/53/UE).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Producent

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Stany Zjednoczone

Przedstawiciel na terenie UE

Boston Scientific Limited
Ballybrit Business Park
Galway
Irlandia

Boston Scientific Neuromodulation Corporation ponosi wyłączną odpowiedzialność za deklarację zgodności.

Podpisano w imieniu i na rzecz: Boston Scientific Neuromodulation Corporation

Data wydania:

DocuSigned by:



Signer Name: Rafael Carbunaru

Signing Reason: I approve this document

Wiceprezident, Boston Scientific Neuromodulation Corporation

Signature Time: 19 October 2021 12:44 PM PDT
A5027EA413014C698C88320E44410619

Miejsce wydania: Valencia, CA USA

19 October 2021

Data złożenia podpisu

Megfelelőségi nyilatkozat
Rádióberendezésekről szóló irányelv (2014/53/EU)
Magyar

Kibocsátó neve: Boston Scientific Neuromodulation Corporation
Kibocsátó címe: 25155 Rye Canyon Loop
Valencia, CA 91355
Amerikai Egyesült Államok
A nyilatkozat tárgya: Vercise Genus™ mélyagyi stimulációs rendszer
WaveWriter Alpha™ rendszer

A jelen megfelelőségi nyilatkozat a következő típusokra vonatkozik: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

A fent leírt nyilatkozat tárgyát képező készülékek megfelelnek a vonatkozó harmonizált EU-s törvényeknek, valamint az alábbi dokumentumoknak: Rádióberendezésekről szóló irányelv (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Gyártó

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Amerikai Egyesült Államok

EK-képviselő

Boston Scientific Limited
Ballybrit Business Park
Galway
Írország

A megfelelőségi nyilatkozattal kapcsolatban a felelősséget kizárólag a Boston Scientific Neuromodulation Corporation viseli.

Aláírva a következő vállalat részéről és megbízásából: Boston Scientific Neuromodulation Corporation

Kiállítás dátuma:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Signing Time: 19 October 2021 6:52:49 PM PDT
A5027EA413014C698C88320E44410619

Kiállítás helye: Valencia, CA

19 October 2021

Aláírás dátuma

Декларация за съответствие
Директива за радиосъоръжения (2014/53/EC)
Български

Име на емитента: Boston Scientific Neuromodulation Corporation
Адрес на емитента: 25155 Rye Canyon Loop
Valencia, CA 91355
Съединени американски щати
Обект на декларацията: Система за дълбокомозъчна стимулация Vercise Genus™
Система WaveWriter Alpha™

Моделите, за които се отнася тази декларация за съответствие, са: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Обектът на декларацията, описана по-горе, е в съответствие със съответното хармонизирано законодателство на Съюза и следните документи: Директива за радиосъоръжения (2014/53/EC).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Производител

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Съединени американски щати

Представител за ЕО

Boston Scientific Limited
Ballybrit Business Park
Galway
Ирландия

Boston Scientific Neuromodulation Corporation носи изключителната отговорност за Декларацията за съответствие.

Подписано за и от името на: Boston Scientific Neuromodulation Corporation

Дата на издаване:

DocuSigned by:



Signer Name: Rafael Carbunaru

Signing Reason: I approve this document

Вицезгенерален директор за изследвания и разработка

Signature Date: 19 October 2021 16:52:44 UTC
A5027EA413014C698C88320E44410619

Място на издаване: Valencia, CA

19 october 2021

Дата на подписването

Izjava o usklađenosti
Direktiva o radioopremi (2014/53/EU)
Hrvatski

Naziv izdavača: Boston Scientific Neuromodulation Corporation
Adresa izdavača: 25155 Rye Canyon Loop
Valencia, CA 91355
Sjedinjene Američke Države
Predmet izjave: Vercise Genus™ Sustav za stimulaciju dubokih struktura mozga
Sustav WaveWriter Alpha™

Modeli koji su spomenuti u ovoj Izjavi o sukladnosti su: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Cilj prethodno opisane izjave u skladu je s relevantnim zakonodavstvom Unije te sljedećim dokumentima: Direktiva o radioopremi (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Proizvođač
Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Sjedinjene Američke Države

Predstavnik za EU
Boston Scientific Limited
Ballybrit Business Park
Galway
Irska

Tvrtka Boston Scientific Neuromodulation Corporation isključivo je odgovorna za Izjavu o sukladnosti.

Potpisana u ime i za: Boston Scientific Neuromodulation Corporation

Datum izdavanja:

DocuSigned by:



Signer Name: Rafael Carbunaru

Signing Reason: I approve this document

Potpisano elektronički za Odstaživanje izjave

Potpisano elektronički za Odstaživanje izjave
A5027EA413014C698C88320E44410619

Mjesto izdavanja: Valencia, CA

19 october 2021

Datum potpisa

Declarație de conformitate
Directiva privind echipamentele radio (2014/53/UE)
Română

Denumirea emitentului: Boston Scientific Neuromodulation Corporation
Adresa emitentului: 25155 Rye Canyon Loop
Valencia, CA 91355
Statele Unite ale Americii
Obiectul declarației: Sistem de stimulare cerebrală profundă Vercise Genus™
Sistem WaveWriter Alpha™

Modelele la care se referă această Declarație de conformitate sunt: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Obiectul declarației, descris mai sus, este conform cu legislația armonizată aplicabilă a Uniunii și cu următoarele documente: Directiva privind echipamentele radio (2014/53/UE).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Producător

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Statele Unite ale Americii

Reprezentant în CE

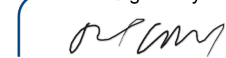
Boston Scientific Limited
Ballybrit Business Park
Galway
Irlanda

Boston Scientific Neuromodulation Corporation răspunde exclusiv pentru Declarația de conformitate.

Semnat pentru și în numele: Boston Scientific Neuromodulation Corporation

Data emiterii:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Signed on: 19 October 2021 16:59:04 PM PDT
A5027EA413014C698C88320E44410619

Locul emiterii: Valencia, CA

19 october 2021

Data semnării

Uyumluluk Beyanı
Radjo Ekipmanı Direktifi (2014/53/EU)
Türkçe

Düzenleyenin Adı: Boston Scientific Neuromodulation Corporation
Düzenleyenin Adresi: 25155 Rye Canyon Loop
Valencia, CA 91355
Amerika Birleşik Devletleri
Beyan konusu: Vercise Genus™ Derin Beyin Stimülasyonu Sistemi
WaveWriter Alpha™ Sistemi

Bu Uyumluluk Beyanı için ilgili modeller: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Yukarıda açıklanan beyanın konusu, ilgili Birlik uyumlaştırılmış mevzuatıyla ve aşağıdaki belgelerle uyumludur: Radjo Ekipmanı Direktifi (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Üretici

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Amerika Birleşik Devletleri

AT Temsilcisi

Boston Scientific Limited
Ballybrit Business Park
Galway
İrlanda

Boston Scientific Neuromodulation Corporation, Uyumluluk Beyanından münhasıran sorumludur.

Adına imzalanan şirket: Boston Scientific Neuromodulation Corporation

Düzenlenme Tarihi:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Signing Time: 19 October 2021, 16:36:15 PM EDT
A5027EA413014C698C88320E44410619

Düzenlenme Yeri: Valencia, CA

19 October 2021

İmza Tarihi

Izjava o skladnosti
Direktiva o radijski opremi (2014/53/EU)
Slovenščina

Naziv izdajatelja: Boston Scientific Neuromodulation Corporation
Naslov izdajatelja: 25155 Rye Canyon Loop
Valencia, CA 91355
Združene države Amerike
Predmet izjave: Sistem za globoko možgansko stimulacijo Vercise Genus™
Sistem WaveWriter Alpha™

Modeli, na katere se nanaša ta izjava o skladnosti: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Zgoraj opisani predmet izjave izpolnjuje zahteve ustrezno usklajene zakonodaje Unije in naslednjih dokumentov: Direktiva o radijski opremi (2014/53/EU).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Proizvajalec

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Združene države Amerike

Zastopnik v Evropski skupnosti

Boston Scientific Limited
Ballybrit Business Park
Galway
Irska

Družba Boston Scientific Neuromodulation Corporation je edina odgovorna za izjavo o skladnosti.

Podpisano za in v imenu: Boston Scientific Neuromodulation Corporation

Datum izdaje:

DocuSigned by:



Signer Name: Rafael Carbutaru
Signing Reason: I approve this document
Podpisnik, 19 October 2021 12:39 PM PDT
A5027EA413014C698C88320E44410619

Kraj izdaje: Valencia, Kalifornija

19 October 2021

Datum podpisa

Vastavusdeklaratsioon
Raadioseadmete direktiiv (2014/53/EL)
Eesti

Väljastaja nimi: Boston Scientific Neuromodulation Corporation
Väljastaja aadress: 25155 Rye Canyon Loop
Valencia, CA 91355
Ameerika Ühendriigid
Deklaratsiooni objekt: Vercise Genus™-e peaju süvastimulatsiooni süsteem
WaveWriter Alpha™ süsteem

Selles vastavusdeklaratsioonis käsitletavad mudelid on järgmised: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Ülalpool kirjeldatud deklaratsiooni objekt vastab asjakohastele Euroopa Liidu ühtlustatud õigusaktidele ja järgmistele dokumentidele: raadioseadmete direktiiv (2014/53/EL).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Tootja
Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Ameerika Ühendriigid

EÜ esindaja
Boston Scientific Limited
Ballybrit Business Park
Galway
Iirimaa

Boston Scientific Neuromodulation Corporation on vastavusdeklaratsiooni eest ainuvastutav.

Allkirjastatud järgmise ettevõtte nimel: Boston Scientific Neuromodulation Corporation

Väljastamiskuupäev:

DocuSigned by:


Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Signed on: 19 October 2021 16:33:20 PM PDT
A5027EA413014C698C88320E44410619

Väljastamiskoht: Valencia, CA

19 October 2021

Allkirjastamise kuupäev

Atbilstības deklarācija
Radioiekārtu direktīva (2014/53/ES)
Latviski

Izdevēja nosaukums: Boston Scientific Neuromodulation Corporation
Izdevēja adrese: 25155 Rye Canyon Loop
Valencia, CA 91355
Amerikas Savienotās Valstis
Deklarācijas priekšmets: Vercise Genus™ dziļā smadzeņu stimulācijas sistēma
WaveWriter Alpha™ sistēma

Šajā atbilstības deklarācijā minētie modeļi: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Iepriekš aprakstītais deklarācijas priekšmets atbilst saistošajiem Eiropas Savienības saskaņotajiem tiesību aktiem un šādiem dokumentiem: Radioiekārtu direktīva (2014/53/ES).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Ražotājs

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Amerikas Savienotās Valstis

Pārstāvis Eiropas Kopienā

Boston Scientific Limited
Ballybrit Business Park
Galway
Īrija

Boston Scientific Neuromodulation Corporation ir tikai un vienīgi atbildīgs par atbilstības deklarāciju.

Parakstīts šāda uzņēmuma vārdā: Boston Scientific Neuromodulation Corporation

Izdošanas datums:

Izdošanas vieta: Valensija, Kalifornijas štats

DocuSigned by:


Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Petitioner's Signature: Rafael Carbunaru
Signature Date: 19 October 2021
A5027EA413014C698C88320E44410619

19 October 2021

Paraksta datums

Atitikties deklaracija
Radio įrangos direktyva (2014/53/ES)
Lietuvių k.

Pateikėjo pavadinimas: „Boston Scientific Neuromodulation Corporation“
Pateikėjo adresas: 25155 Rye Canyon Loop
Valencia, CA 91355
Jungtinės Amerikos Valstijos
Deklaracijos objektas: Giliojo smegenų stimuliavimo sistema „Vercise Genus™“
Sistema „WaveWriter Alpha™“

Ši atitikties deklaracija taikoma šiems modeliams: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Pirmiau apibūdintas deklaracijos objektas atitinka atitinkamus Sąjungos suderintus teisės aktus ir šiuos dokumentus: radio įrangos direktyvą (2014/53/ES).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Gamintojas

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355
Jungtinės Amerikos Valstijos

Atstovas EB

Boston Scientific Limited
Ballybrit Business Park
Galway
Airija

Už atitikties deklaraciją išskirtinai atsako „Boston Scientific Neuromodulation Corporation“.

Pasirašyta (kieno vardu): „Boston Scientific Neuromodulation Corporation“

Išdavimo data:

DocuSigned by:



Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Signing Time: 19 October 2021 at 3:36 PM PDT
A5027EA413014C698C88320E44410619

Išdavimo vieta: Valencia, CA

19 October 2021

Pasirašymo data

Samræmisýfirlýsing
Tilskipun um fjarskiptabúnað (2014/53/ESB)
Íslenska

Nafn útgefanda: Boston Scientific Neuromodulation Corporation
Heimilisfang útgefanda: 25155 Rye Canyon Loop
Valencia, CA 91355
Bandaríkin
Varan sem samræmisýfirlýsingin á við: Vercise Genus™ kerfi fyrir djúpheilaörvun
WaveWriter Alpha™ kerfi

Tegundir sem þessi samræmisýfirlýsing á við eru: DB-1408, DB-1416, DB-1432, DB-1216, DB-1232, DB-5170, DB-5270, DB-5572-1A, SC-1216, SC-1232, SC-1416, SC-1432, SC-5170, SC-5170R, SC-12010, SC-12030, SC-14016, SC-14032, SC-5270, SC-5270R, SC-5572-1A

Varan sem samræmisýfirlýsingin á við og lýst er að ofan er í samræmi við viðkomandi samræmislöggjöf ESB og eftirfarandi gögn: Tilskipun um fjarskiptabúnað (2014/53/ESB).

EN 60601-1:2006 +A1:2013
EN 60601-1-2:2015
EN 60601-1-11:2015
ANSI/AAMI/ISO 14708-3:2017
EN ISO 14971:2019
EN 62479:2010
ETSI EN 300 328 V2.2.2:2019
ETSI EN 301 489-1 V2.2.3:2019
ETSI EN 301 489-17 V3.2.4:2020

Framleiðandi

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Galway
Írland

Samræmisýfirlýsingin er eingöngu á ábyrgð Boston Scientific Neuromodulation Corporation.

Undirritað fyrir og fyrir hönd: Boston Scientific Neuromodulation Corporation

Útgáfudagur:

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Signer Name: Rafael Carbunaru
Signing Reason: I approve this document
Signing time: 15 October 2021 06:34:11 PM PST
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Útgáfustaður: Valencia, CA

19 October 2021

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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	10/12/2021 11:06:27 AM
Certified Delivered	Security Checked	10/19/2021 6:50:31 PM
Signing Complete	Security Checked	10/19/2021 6:54:52 PM
Completed	Security Checked	10/19/2021 6:54:52 PM
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Email:	Access to a valid email account
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