Boston Scientific
Advancing science for life™

Radio Equipment Directive (RED) Compliance – EU Declaration of Conformity Spinal Cord Stimulator Systems

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

Issuer's Name: Boston Scientific Neuromodulation Corporation
Issuer's Address: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

Object of the declaration: Precision™ Spinal Cord Stimulator System
(Precision™ System)
Precision Spectra™ Spinal Cord Stimulator System
(Precision Spectra™ System)
Precision Novi™ Spinal Cord Stimulator System
(Precision Novi™ System)
Precision™ Montage™ MRI Spinal Cord Stimulator System
(Precision™ Montage™ MRI System)
Precision™ Montage™ Spinal Cord Stimulator System
(Precision™ Montage™ System)
Spectra WaveWriter™ Spinal Cord Stimulator System
(Spectra WaveWriter™ System)

The Precision SCS device family models addressed by this Declaration of Conformity are:
Precision™ System: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™ System: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™ System: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™ and Precision™ Montage™ MRI Systems: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™ System: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Place of Issue: Valencia, California

Adele Shoustal
Director of Regulatory Affairs

02AUG2019
Date of Signature

Boston Scientific
Advancing science for life™

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

Nombre del emisor: Boston Scientific Neuromodulation Corporation
Dirección del emisor: 25155 Rye Canyon Loop
Valencia, CA 91355
EE. UU.

Objeto de la declaración: Sistema de estimulación de la médula espinal (EME) Precision™ (Sistema Precision™)
Sistema de estimulación de la médula espinal Precision Spectra™ (Sistema Precision Spectra™)
Sistema de estimulación de la médula espinal Precision Novi™ (Sistema Precision Novi™)
Sistema de estimulación de la médula espinal RM Precision™ Montage™ (Sistema de RM Precision™ Montage™)
Sistema de estimulación de la médula espinal Precision™ Montage™ (Sistema Precision™ Montage™)
Sistema de estimulación de la médula espinal Spectra WaveWriter™ (Sistema Spectra WaveWriter™)

Los modelos de la gama de dispositivos de EME Precision afectados por esta Declaración de conformidad son los siguientes:
Sistema Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Sistema Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Sistema Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Sistemas de RM Precision™ Montage™ y Precision™ Montage™: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Sistema Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Fabricante

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

Representante de la CE

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: 02AUG2019

Lugar de emisión: Valencia, California

Adele Shoustal
Directora de asuntos reglamentarios

02AUG2019
Fecha de la firma

Boston Scientific
Advancing science for life™

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

Nom de l'émetteur : Boston Scientific Neuromodulation Corporation
Adresse de l'émetteur : 25155 Rye Canyon Loop
Valencia, CA 91355, États-Unis
États-Unis

Objet de la déclaration : Précision™ Système de stimulation de la moelle épinière (Precision™ System)
Precision Spectra™ Système de stimulation de la moelle épinière (Système Precision Spectra™)
Precision Novi™ Système de stimulation de la moelle épinière (Système Precision™ Novi)
Precision™ Montage™ MRI Système de stimulation de la moelle épinière (Système ™Montage™ MRI)
Precision™ Montage™ Système de stimulation de la moelle épinière (Système Precision™ Montage™)
Spectra WaveWriter™ Système de stimulation de la moelle épinière (Système Spectra WaveWriter™)

Les modèles de la famille d'appareils Precision SCS visés par la présente déclaration de conformité sont :
Precision™ System : SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Système Precision Spectra™ : SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Système Precision™ Novi : SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™ et Precision™ Montage™ Montage™ Systèmes d'IRM : SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Système Spectra WaveWriter™ : SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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/EU)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Fabricant

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

Représentant de la CE

Boston Scientific Limited
Ballybrit Business Park
Galway
Irelande

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 : 02AUG2019

Lieu de délivrance : Valence (Californie)

Adele Shoustal
Directeur des affaires réglementaires

02 AUG 2019
Date de signature

Boston Scientific
Advancing science for life™

Konformitätserklärung
Funkgeräterichtlinie (2014/53/EU)

Name des Herausgebers:	Boston Scientific Neuromodulation Corporation
Adresse des Herausgebers:	25155 Rye Canyon Loop Valencia, CA 91355 USA
Gegenstand der Erklärung:	Precision™-Rückenmarkstimulationssystem (Precision™-System) Precision Spectra™-Rückenmarkstimulationssystem (Precision Spectra™-System) Precision Novi™-Rückenmarkstimulationssystem (Precision Novi™-System) Precision™ Montage™ MRI-Rückenmarkstimulationssystem (Precision™ Montage™ MRI-System) Precision™ Montage™-Rückenmarkstimulationssystem (Precision™ Montage™-System) Spectra WaveWriter™-Rückenmarkstimulationssystem (Spectra WaveWriter™-System)

Die in dieser Konformitätserklärung angesprochenen Geräte der Precision SCS-Familie sind:
Precision™-System: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™-System: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™-System: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™- und Precision™ Montage™ MRI-Systeme: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™-System: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Hersteller

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

Autorisierter Vertreter der Europäischen Union:

Boston Scientific Limited
Ballybrit Business Park
Galway
Irland

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

Unterzeichnet für und im Namen von: Boston Scientific Neuromodulation Corporation

Ausgabedatum: 02AUG2019

Ausgabeort: Valencia, California

Adele Shoustal
Director of Regulatory Affairs

02AUG2019
Datum der Unterschrift

Boston Scientific
Advancing science for life™

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

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 per lastimolazione del midollo spinale Precision™ (Sistema Precision™) Sistema per la stimolazione del midollo spinale Precision Spectra™ (Sistema Precision Spectra™) Sistema per la stimolazione del midollo spinale Precision Novi™ (Sistema Precision Novi™) Sistema per la stimolazione del midollo spinale Precision™ Montage™ RM (Sistema Precision™ Montage™ RM) Sistema per la stimolazione del midollo spinale Precision™ Montage™ (Sistema Precision™ Montage™) Sistema per la stimolazione del midollo spinale Spectra WaveWriter™ (Sistema Spectra WaveWriter™)

I modelli della famiglia di dispositivi Precision SCS interessati dalla presente Dichiarazione di Conformità sono:

Sistema Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Sistema Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Sistema Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Sistemi RM Precision™ Montage™ e Precision™ Montage™: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Sistema Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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/EU)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Luogo di emissione: Valencia, California

Adele Shoustal
Responsabile Affari normativi

02AUG2019
Data della firma

Boston Scientific
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Verklaring van conformiteit.
Richtlijn betreffende radioapparatuur (2014/53/EG)

Naam van de uitgever: Boston Scientific Neuromodulation Corporation
Adres van de uitgever: 25155 Rye Canyon Loop
Valencia, CA 91355
VS

Onderwerp van de verklaring: Precision™ ruggenmergstimulatiesysteem
(Precision™ systeem)
Precision Spectra™ ruggenmergstimulatiesysteem
(Precision Spectra™ systeem)
Precision Novi™ ruggenmergstimulatiesysteem
(Precision Novi™ systeem)
Precision™ Montage™ MRI ruggenmergstimulatiesysteem
(Precision™ Montage™ MRI-systeem)
Precision™ Montage™ ruggenmergstimulatiesysteem
(Precision™ Montage™ systeem)
Spectra WaveWriter™ ruggenmergstimulatiesysteem
(Spectra WaveWriter™ systeem)

De modellen van de Precision SCS-apparaatfamilie behandeld door deze conformiteitsverklaring zijn:

Precision™ systeem: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™ systeem: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™ systeem: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™ en Precision™ Montage™ MRI-systemen: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™ systeem: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Fabrikant

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

Vertegenwoordiger in de EU

Boston Scientific Limited
Ballybrit Business Park
Galway
Ierland

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

Ondertekend voor en namens: Boston Scientific Neuromodulation Corporation

Datum van uitgave: 02AUG2019

Plaats van uitgave: Valencia, Californië

Adele Shoustal
Directeur reglementaire zaken

02AUG2019
Datum van ondertekening

Boston Scientific
Advancing science for life™

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

Utgivarens namn: Boston Scientific Neuromodulation Corporation
Utgivarens adress: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

Försäkran omfattar följande system:
Precision™-ryggmärgsstimuleringssystem (Precision™-system)
Precision Spectra™-ryggmärgsstimuleringssystem (Precision Spectra™-system)
Precision Novi™-ryggmärgsstimuleringssystem (Precision Novi™-system)
Precision™ Montage™-MR-ryggmärgsstimuleringssystem (Precision™ Montage™-MR-system)
Precision™ Montage™-ryggmärgsstimuleringssystem (Precision™ Montage™-system)
Spectra WaveWriter™-ryggmärgsstimuleringssystem (Spectra WaveWriter™-system)

Försäkran omfattar följande Precision SCS-modeller:
Precision™-system: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™-system: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™-system: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™- och Precision™ Montage™-MR-system: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™-system: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Utgivningsort: Valencia, Kalifornien

Adele Shoustal
Director of Regulatory Affairs

02 AUG 2019
Datum

Boston Scientific
Advancing science for life™

Vaatimustenmukaisuusvakuutus
Radiolaitedirektiivi (2014/53/EU)

Julkaisijan nimi: Boston Scientific Neuromodulation Corporation
Julkaisijan osoite: 25155 Rye Canyon Loop
Valencia, CA 91355
Yhdysvallat

Vakuutuksen kohde:
Precision™-selkäydinstimulaatiojärjestelmä
(Precision™-järjestelmä)
Precision Spectra™ -selkäydinstimulaatiojärjestelmä
(Precision Spectra™ -järjestelmä)
Precision Novi™ -selkäydinstimulaatiojärjestelmä
(Precision Novi™ -järjestelmä)
Precision™ Montage™ MRI -selkäydinstimulaatiojärjestelmä
(Precision™ Montage™ MRI -järjestelmä)
Precision™ Montage™ -selkäydinstimulaatiojärjestelmä
(Precision™ Montage™ -järjestelmä)
Spectra WaveWriter™ -selkäydinstimulaatiojärjestelmä
(Spectra WaveWriter™ -järjestelmä)

Precision SCS -laiteperheen mallit, joita tämä vaatimustenmukaisuusvakuutus koskee, ovat seuraavat:
Precision™-järjestelmä: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™ -järjestelmä: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™ -järjestelmä: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™- ja Precision™ Montage™ MRI -järjestelmät: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™ -järjestelmä: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Julkaisupaikka: Valencia, Kalifornia

Adele Shoustal
Sääntelyasioista vastaava johtaja

02 AUG 2019
Allekirjoituspäivä

Boston Scientific
Advancing science for life™

Samsvarserklæring
Radiodirektivet (2014/53/EU)

Utstederens navn: Boston Scientific Neuromodulation Corporation
Utstederens adresse: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

Erklæringen gjelder:
Precision™ryggmargsstimulatorsystem
(Precision™-systemet)
Precision Spectra™ryggmargsstimulatorsystem
(Precision Spectra™-systemet)
Precision Novi™-ryggmargsstimulatorsystem
(Precision Novi™-systemet)
Precision™ Montage™ MR-ryggmargsstimulatorsystem
(Precision™ Montage™ MR-systemet)
Precision™ Montage™-ryggmargsstimulatorsystem
(Precision™ Montage™-systemet)
Spectra WaveWriter™-ryggmargsstimulatorsystem
(Spectra WaveWriter™-systemet)

Modellene i Precision SCS-utstyrsserien som er behandlet i denne erklæringen, er:
Precision™-systemet: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™-systemet: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™-systemet: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™- og Precision™ Montage™ MR-systemet: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™-systemet: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Produsent

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

Representant i EF

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: 02AUG2019

Sted for utstedelse: Valencia, California

Adele Shoustal
Director of Regulatory Affairs

02 AUG 2019
Dato for signering

Boston Scientific
Advancing science for life™

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

Udstederens navn: Boston Scientific Neuromodulation Corporation
Udstederens adresse: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

Erklæringens formål:
Precision™ -rygmarvsstimuleringssystem
(Precision™-system)
Precision Spectra™-rygmarvsstimuleringssystem
(Precision Spectra™-system)
Precision Novi™-rygmarvsstimuleringssystem
(Precision Novi™-system)
Precision™ Montage™ MR-rygmarvsstimuleringssystem
(Precision™ Montage™ MR-system)
Precision™ Montage™-rygmarvsstimuleringssystem
(Precision™ Montage™-system)
Spectra WaveWriter™-rygmarvsstimuleringssystem
(Spectra WaveWriter™-system)

Precision SCS-enhedens familiemodeller, som denne overensstemmelseserklæring henvender sig til, er:
Precision™-system: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™-system: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™-system: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™ og Precision™ Montage™ MR-systemer: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™-system: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

Formålet med erklæringen beskrevet ovenfor er i overensstemmelse med relevant fagforeningsharmoniseret lovgivning og følgende dokumenter: Radio Equipment Directive (Radioudstyrsdirektivet) (2014/53/EU)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Producent

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

Repræsentant for EU

Boston Scientific Limited
Ballybrit Business Park
Galway
Irland

Boston Scientific Neuromodulation Corporation er alene ansvarlige for overensstemmelseserklæringen.

Underskrevet for og på vegne af: Boston Scientific Neuromodulation Corporation

Udstedelsesdato: 02AUG2019

Udstedelsessted: Valencia, Californien

Adele Shoustal
Direktør for Regulatory Affairs

02AUG2019
Underskrivelsesdato

Boston Scientific
Advancing science for life™

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

Nome do emissor: Boston Scientific Neuromodulation Corporation
Endereço do emissor: 25155 Rye Canyon Loop
Valencia, CA 91355
EUA

Objeto da declaração: Sistema de estimulação da medula espinal Precision™ (Sistema Precision™)
Sistema de estimulação da medula espinal Precision Spectra™ (Sistema Precision Spectra™)
Sistema de estimulação da medula espinal Precision Novi™ (Sistema Precision Novi™)
Sistema de estimulação da medula espinal Precision™ RM Montage™ (Sistema Precision™ RM Montage™)
Sistema de estimulação da medula espinal Precision™ Montage™ (Sistema Precision™ Montage™)
Sistema de estimulação da medula espinal Spectra WaveWriter™ (Sistema Spectra WaveWriter™)

Os modelos da família de dispositivos SCS Precision abordados por esta Declaração de Conformidade são os seguintes:
Sistema Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Sistema Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Sistema Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Sistemas Precision™ Montage™ e Precision™ RM Montage™: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Sistema Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Local de emissão: Valencia, Califórnia

Adele Shoustal
Diretora de Assuntos Regulamentares

02 AUG 2019
Data da assinatura

Boston Scientific
Advancing science for life™

Uyumluluk Beyanı
Radyo Ekipmanı Direktifi (2014/53/EU)

Düzenleyenin Adı: Boston Scientific Neuromodulation Corporation
Düzenleyenin Adresi: 25155 Rye Canyon Loop
Valencia, CA 91355
ABD

Beyannamenin konusu: Precision™ Omurilik Stimülatör Sistemi
(Precision™ Sistemi)
Precision Spectra™ Omurilik Stimülatör Sistemi
(Precision Spectra™ Sistemi)
Precision Novi™ Omurilik Stimülatör Sistemi
(Precision Novi™ Sistemi)
Precision™ Montage™ MRI Omurilik Stimülatör Sistemi
Precision™ Montage™ MRI Sistemi
Precision™ Montage™ Omurilik Stimülatör Sistemi
Precision™ Montage™ Sistemi
Spectra WaveWriter™ Omurilik Stimülatör Sistemi
(Spectra WaveWriter™ Sistemi)

Bu Uyumluluk Beyanı ile ele alınan Precision SCS cihaz ailesi modelleri şunlardır:
Precision™ Sistemi: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™ Sistemi: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™ Sistemi: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™ ve Precision™ Montage™ MRI Sistemleri: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™ Sistemi: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Düzenlenme Yeri: Valencia, California

Adele Shoustal
Ruhsat İşleri Yöneticisi

02 AUG 2019
İmza Tarihi

Boston Scientific
Advancing science for life™

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

Όνομα εκδότη: Boston Scientific Neuromodulation Corporation
Διεύθυνση εκδότη: 25155 Rye Canyon Loop
Valencia, CA 91355
ΗΠΑ

Αντικείμενο της δήλωσης: Σύστημα διέγερσης νωτιαίου μυελού Precision™
(Σύστημα Precision™)
Σύστημα διέγερσης νωτιαίου μυελού Precision Spectra™
(Σύστημα Precision Spectra™)
Σύστημα διέγερσης νωτιαίου μυελού Precision Novi™
(Σύστημα Precision Novi™)
Σύστημα διέγερσης νωτιαίου μυελού Precision™ Montage™ MRI
(Σύστημα MRI Precision™ Montage™)
Σύστημα διέγερσης νωτιαίου μυελού Precision™ Montage™
(Σύστημα Precision™ Montage™)
Σύστημα διέγερσης νωτιαίου μυελού Spectra WaveWriter™
(Σύστημα Spectra WaveWriter™)

Τα μοντέλα της σειράς συσκευών Precision SCS που καλύπτονται από αυτήν τη δήλωση συμμόρφωσης είναι:
Σύστημα Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Σύστημα Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Σύστημα Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Συστήματα Precision™ Montage™ και Precision™ Montage™ MRI: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Σύστημα Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Κατασκευαστής

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

Αντιπρόσωπος ΕΚ

Boston Scientific Limited
Ballybrit Business Park
Galway
Ιρλανδία

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

Υπογραφή για λογαριασμό και εξ ονόματος: Boston Scientific Neuromodulation Corporation

Ημερομηνία Έκδοσης: 02AUG2019

Τόπος έκδοσης: Valencia, California

Adele Shoustal
Διευθύντρια ρυθμιστικών υποθέσεων

02 AUG 2019
Ημερομηνία υπογραφής

Boston Scientific
Advancing science for life™

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

Název vydavatele: Boston Scientific Neuromodulation Corporation
Adresa vydavatele: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

Předmět prohlášení:
Systém stimulace míchy Precision™
(systém Precision™)
Systém stimulace míchy Precision Spectra™
(systém Precision Spectra™)
Systém stimulace míchy Precision Novi™
(systém Precision Novi™)
Systém stimulace míchy Precision™ Montage™ MRI
(systém Precision™ Montage™ MRI)
Systém stimulace míchy Precision™ Montage™
(systém Precision™ Montage™)
Systém stimulace míchy Spectra WaveWriter™
(systém Spectra WaveWriter™)

Modely skupiny zařízení Precision SCS řešené tímto prohlášením o shodě jsou:
Systém Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Systém Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Systém Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Systémy Precision™ Montage™ a Precision™ Montage™ MRI: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Systém Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Místo vydání: Valencia, Kalifornie

Adele Shoustal
Adele Shoustal
ředitelka pro regulatorní záležitosti

02AUG2019
Datum podpisu

Boston Scientific
Advancing science for life™

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

Názov vydavateľa: Boston Scientific Neuromodulation Corporation
Adresa vydavateľa: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

Predmet vyhlásenia:
systém stimulácie miechy Precision™
(systém Precision™)
systém stimulácie miechy Precision Spectra™
(systém Precision Spectra™)
systém stimulácie miechy Precision Novi™
(systém Precision Novi™)
systém stimulácie miechy Precision™ Montage™ MRI
(systém Precision™ Montage™ MRI)
systém stimulácie miechy Precision™ Montage™
(systém Precision™ Montage™)
systém stimulácie miechy Spectra WaveWriter™
(systém Spectra WaveWriter™)

Modely série zariadení Precision SCS, ktorých sa týka toto vyhlásenie o zhode:
Systém Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Systém Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Systém Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Systémy Precision™ Montage™ a Precision™ Montage™ MRI: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Systém Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Miesto vydania: Valencia, California

Adele Shoustal
Vedúca oddelenia regulačných záležitostí

02AUG2019
Dátum podpisu

Boston Scientific
Advancing science for life™

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

Imię i nazwisko wydawcy: Boston Scientific Neuromodulation Corporation
Adres wydawcy: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

Przedmiot zgodności:
System stymulacji rdzenia kręgowego Precision™ (System Precision™)
System stymulacji rdzenia kręgowego Precision Spectra™ (System Precision Spectra™)
System stymulacji rdzenia kręgowego Precision Novi™ (System Precision Novi™)
System stymulacji rdzenia kręgowego Precision™ Montage™ MRI (System Precision™ Montage™ MRI)
System stymulacji rdzenia kręgowego Precision™ Montage™ (System Precision™ Montage™)
System stymulacji rdzenia kręgowego Spectra WaveWriter™ (System Spectra WaveWriter™)

Urządzenia modeli z rodziny Precision SCS, których dotyczy niniejsza deklaracja zgodności, to:
System Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

System Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

System Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Systemy Precision™ Montage™ i Precision™ Montage™ MRI: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

System Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Miejsce wydania: Valencia, Kalifornia

Adele Shoustal
Dyrektor ds. regulacji prawnych

02 AUG 2019
Data złożenia podpisu

Boston Scientific
Advancing science for life™

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

Kibocsátó neve: Boston Scientific Neuromodulation Corporation
Kibocsátó címe: 25155 Rye Canyon Loop
Valencia, CA 91355
USA

A nyilatkozat tárgya:

Precision™ gerincvelői stimulációs rendszer
(Precision™ rendszer)

Precision Spectra™ gerincvelői stimulációs rendszer
(Precision Spectra™ rendszer)

Precision Novi™ gerincvelői stimulációs rendszer
(Precision Novi™ rendszer)

Precision™ Montage™ MRI gerincvelői stimulációs rendszer
(Precision™ Montage™ MRI rendszer)

Precision™ Montage™ gerincvelői stimulációs rendszer
(Precision™ Montage™ rendszer)

Spectra WaveWriter™ gerincvelői stimulációs rendszer
(Spectra WaveWriter™ rendszer)

A Precision SCS készülékcsalád jelen megfelelőségi nyilatkozat által érintett modelljei:
Precision™ rendszer: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Precision Spectra™ rendszer: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Precision Novi™ rendszer: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Precision™ Montage™ és Precision™ Montage™ MRI rendszerek: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Spectra WaveWriter™ rendszer: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Kiállítás helye: Valencia, California

Adele Shoustal
Igazgató, szabályozási ügyek

02AUG2019
Aláírás dátuma

Boston Scientific
Advancing science for life™

Декларация за съответствие
Директива за радиосъоръжения (2014/53/ЕС)

Име на емитента: Boston Scientific Neuromodulation Corporation
Адрес на емитента: 25155 Rye Canyon Loop
Valencia, CA 91355
САЩ

Обект на декларацията: Система за стимулация на гръбначен мозък Precision™ (Система Precision™)

Система за стимулация на гръбначен мозък Precision Spectra™ (Система Precision Spectra™)

Система за стимулация на гръбначен мозък Precision Novi™ (Система Precision Novi™)

Система за стимулация на гръбначен мозък ЯМР Precision™ Montage™ (Система ЯМР Precision™ Montage™)

Система за стимулация на гръбначен мозък Precision™ Montage™ (Система Precision™ Montage™)

Система за стимулация на гръбначен мозък Spectra WaveWriter™ (Система Spectra WaveWriter™)

Моделите на семейството устройства за стимулация на гръбначен мозък Precision, предмет на настоящата Декларация за съответствие, са:

Система Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Система Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Система Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Системи Precision™ Montage™ и ЯМР Precision™ Montage™: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Система Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

Обектът на гореописаната декларация е в съответствие със съответното хармонизирано законодателство на Европейския съюз и следните документи: Директива за радиосъоръжения (2014/53/ЕС)

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Производител

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

Представител за ЕС

Boston Scientific Limited
Ballybrit Business Park
Galway
Ирландия

Отговорността за Декларацията за съответствие е изключително на Boston Scientific Neuromodulation Corporation.

Подписано за и от името на: Boston Scientific Neuromodulation Corporation

Дата на издаване: 02AUG2019

Място на издаване: Valencia, California

Adele Shoustal
Директор по регулаторни въпроси

02 AUG 2019
Дата на подпис

Boston Scientific
Advancing science for life™

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

Naziv izdavača: Boston Scientific Neuromodulation Corporation
Adresa izdavača: 25155 Rye Canyon Loop
Valencia, CA 91355
SAD

Predmet izjave:

Precision™ sustav stimulatora za kralježničnu moždinu (Precision™ sustav)

Precision Spectra™ sustav stimulatora za kralježničnu moždinu (Sustav Precision Spectra™)

Precision Novi™ sustav stimulatora za kralježničnu moždinu (Sustav Precision Novi™)

Precision™ Montage™ MRI sustav stimulatora za kralježničnu moždinu (Sustav Precision Montage™ MRI)

Precision Montage™ MRI sustav stimulatora za kralježničnu moždinu (Sustav Precision Montage™ MRI)

Spectra WaveWriter™ sustav stimulatora za kralježničnu moždinu (Spectra WaveWriter™ sustav)

Obiteljski modeli uređaja Precision SCS koji su spomenuti u ovoj Izjavi o sukladnosti su:
Precision™ sustav: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Sustav Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Sustav Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Sustavi Precision™ Montage™ i Precision™ Montage™ MRI: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Sustav Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

Proizvođač

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

Ovlašteni predstavnik za EU

Boston Scientific Limited
Ballybrit Business Park
Galway
Irska

Boston Scientific Neuromodulation Corporation isključivo je odgovorn za Izjavu o sukladnosti.

Potpisana u ime i za:: Boston Scientific Neuromodulation Corporation

Datum izdavanja: 02AUG2019

Mjesto izdavanja: Valencia, California

Adele Shoustal
Direktor regulatornih poslova

02AUG2019
Datum potpisa

Boston Scientific
Advancing science for life™

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

Denumirea emitentului: Boston Scientific Neuromodulation Corporation
Adresa emitentului: 25155 Rye Canyon Loop
Valencia, CA 91355
S.U.A.

Obiectul declarației:
Sistemul de stimulare a măduvei spinării Precision™ (Sistemul Precision™)
Sistemul de stimulare a măduvei spinării Precision Spectra™ (Sistemul Precision Spectra™)
Sistemul de stimulare a măduvei spinării Precision Novi™ (Sistemul Precision Novi™)
Sistemul de stimulare a măduvei spinării Precision™ IRM Montage™ (Sistemul Precision™ IRM Montage™)
Sistemul de stimulare a măduvei spinării Precision™ Montage™ (Sistemul Precision™ Montage™)
Sistemul de stimulare a măduvei spinării Spectra WaveWriter™ (Sistemul Spectra WaveWriter™)

Modelele din gama de dispozitive SCS (de stimulare a măduvei spinării) Precision la care se referă această Declarație de conformitate sunt:
Sistemul Precision™: SC-1110-02, SC-1112, SC-5110, SC-5112, SC-5212, SC-5213, SC-5500-4, SC-5312, SC-6412-3

Sistemul Precision Spectra™: SC-1132, SC-5132, NM-7190, SC-5232, SC-5532-1, SC-5532-1A, SC-5312, SC-6412-3

Sistemul Precision Novi™: SC-1140, SC-5132, NM-7190, SC-5240, SC-5542-1A, SC-1042-A

Sistemele Precision™ Montage™ și Precision™ IRM Montage™: SC-1120, SC-1200, SC-5132, NM-7190, SC-5250, SC-5552-1A, SC-5312, SC-6412-3, SC-1210B

Sistemul Spectra WaveWriter™: SC-1160, SC-5160, SC-5160R, SC-5260, SC-5562-1A, NM-7190, SC-5312, SC-6412-3.

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

ETSI EN 301 489-1 V2.1.1:2016
ETSI EN 301 489-31 V2.1.1:2016
ETSI EN 302 195 V2.1.1:2016
EN ISO 14971:2012
EN 45502-1:2015
EN 60601-1:2006/A1:2013
EN 60601-1-11:2015
EN 60601-1-2:2015
EN 62311:2008

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: 02AUG2019

Locul emiterii: Valencia, California

Adele Shoustal
Director de reglementare

02 AUG 2019
Data semnării