Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough
MA 01752
USA
SRN ID.: US-MF-000004702

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 3812454CN

Additional certificate: 3830129TD01, 2258731TD01, 3830530TD01, 3830850TD01, 3831050TD01, 3831192TD01, 3832167TD01, 2262439TD01, 3831571TD01, 3832142TD01, 3830129TD02, 3830129TD03, 3830129TD04, 3830129TD05, 2271842TD01

Authorized Representative: Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland.

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

D[redacted].

B.
M

First Issued: **25 October 2022** Date: **12 February 2024** Expiry date: **25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, Class Is) **Sterilization method: Gamma Irradiation**
Device Name: ACURATE neo2 Loading Kit

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, Class Is) **Sterilization method: EtO**
Device Name: wireClip Torquer

General non-active non-implantable device used in health care and other non-active non-implantable devices (MDN1213, Class Is) **Sterilization method: Gamma Irradiation**
Device Name: Disposable Pullback Sled for Motordrive

General non-active non-implantable devices used in health care and other non-active non-implantable devices (MDN1214, Class Is) **Sterilization method:** E-Beam Irradiation
Device Name: MDU5 Plus Sterile Bag **Device Name:** Permanent Sled Bag

Active non-implantable imaging devices utilizing non-ionizing radiation (NBOG MDA0202, Class IIa)
Device Name: AVVIGO Guidance System II **Device Name:** AVVIGO+ Guidance System

Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools (MDN1203, Class IIa)
Device Name: iSLEEVE Introducer Set

First Issued: **25 October 2022** Date: **12 February 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Class III
Device Name: ACURATE neo2 Aortic Valve
Device Name: ACURATE neo2 Transfemoral Delivery System
Device Name: SYNERGY XD Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: SYNERGY MEGATRON Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: SYNERGY SHIELD Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Maverick2 Monorail PTCA Dilatation Catheter
Device Name: ROTAWIRE Drive and wireClip Torquer
Device Name: Guidezilla II Guide Extension Catheter
Device Name: Guidezilla II LONG Guide Extension Catheter
Device Name: SENTINEL Cerebral Protection System
Device Name: Emerge MONORAIL PTCA Dilatation Catheter
Device Name: Emerge Push MONORAIL PTCA Dilatation Catheter
Device Name: Emerge OVER-THE-WIRE PTCA Dilatation Catheter
Device Name: Emerge Push OVER-THE-WIRE PTCA Dilatation Catheter
Device Name: NC Emerge Monorail PTCA Dilatation Catheter
Device Name: NC Quantum Apex Monorail PTCA Dilatation Catheter
Device Name: Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Promus PREMIER Select Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Promus ELITE Everolimus-Eluting Platinum Chromium Coronary Stent System
Device Name: Ultra ICE Plus 9 MHz IntraCardiac Echo Catheter
Device Name: OptiCross Coronary Imaging Catheter
Device Name: OptiCross 6 Coronary Imaging Catheter
Device Name: OptiCross HD Coronary Imaging Catheter
Device Name: OptiCross 6 HD Coronary Imaging Catheter
Device Name: Wolverine Coronary Cutting Balloon MONORAIL Microsurgical Dilatation Device
Device Name: MAMBA Microcatheter
Device Name: MAMBA Flex Microcatheter
Device Name: Agent MONORAIL Paclitaxel-Coated PTCA Balloon Catheter

First Issued: **25 October 2022** Date: **12 February 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3830129CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	25 October 2022	3812454CN100	First issue
1	14 November 2022	3812454CN101	Revised
2	30 November 2022	3812454CN101	Revised
3	14 December 2022	3812454CN101	Revised
4	20 March 2023	3812454CN102	Revised
5	3 May 2023	3812454CN102	Revised
6	16 May 2023	3812454CN102	Revised
7	5 June 2023	3812454CN103	Revised
8	16 June 2023	3812454CN103	Revised
9	25 August 2023	3812454CN103	Revised
10	21 September 2023	3812454CN104	Revised
11	1 November 2023	3812454CN104	Revised
12	12 January 2024	3812454CN105	Revised
13	19 January 2024	3812454CN105	Revised
14	12 February 2024	3812454CN106	Revised

First Issued: **25 October 2022** Date: **12 February 2024** Expiry date**: 25 October 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Numeris: 3830129CE01

ES kokybės vadybos sistemos sertifikatas

Atitikties vertinimo reglamento 2017/745 dėl medicinos priemonių IX priedo I ir III skyriai

Gamintojas:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough
MA 01752
JAV
SRN ID.: US-MF-000004702

DEKRA suteikia teisę naudoti toliau pateiktą EB notifikuotosios įstaigos identifikacinį numerį kartu su CE atitikties ženklu ant atitinkamų produktų, atitinkančių reikiamą techninę dokumentaciją ir jiems taikomo ES reglamento nuostatas:

0344

Sertifikato priedas: 3812454CN

Papildomas sertifikatas: 3830129TD01, 2258731TD01, 3830530TD01, 3830850TD01, 3831050TD01, 3831192TD01, 3832167TD01, 2262439TD01, 3831571TD01, 3832142TD01, 3830129TD02, 3830129TD03, 3830129TD04, 3830129TD05, 2271842TD01

Įgaliotasis atstovas: Boston Scientific Limited, Ballybrit Business Park, Galway, Airija.

DEKRA pareiškia, kad pirmiau minėtas gamintojas laikosi atitinkamų ES reglamento 2017/745, įskaitant visus vėlesnius pakeitimus, reikalavimų, susijusių su pirmiau minėtu atitikties vertinimu. Gamintojui / įgaliotajam atstovui taikoma periodinė stebėsena, kaip reikalaujama atliekant taikytiną atitikties vertinimą pagal reglamentą 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus — Vykdomasis direktorius

J. M. McKenzie — Vyriausiasis sertifikavimo vadybininkas

Pirmą kartą išduota: **2022 m. spalio 25 d.** Data: **2024 m. vasario 12 d.** Galioja iki**: 2027 m. spalio 25 d.**

DEKRA Certification B.V. yra notifikuotoji įstaiga, kurios ID Nr. 0344

DEKRA Certification B.V. Meander

1051, 6825 MJ Arnhem, pašto dėžutė 5185, 6802 ED Arnhem, Nyderlandai
Tel. +31 88 96 83000 www.dekra.nl Įmonės kodas 09085396

2184-6

Numeris: 3830129CE01

ES kokybės vadybos sistemos sertifikatas

Atitikties vertinimo reglamento 2017/745 dėl medicinos priemonių IX priedo I ir III skyriai

Šis sertifikatas taikomas šiai (-ioms) priemonei (-ėms) ir (arba) priemonių grupėms:

Neaktyvūs neimplantuojami kreipiamieji kateteriai, balioniniai kateteriai, kreipiamosios vielos, įvadai, filtrai ir susijusios priemonės (MDN1203, Is klasė) **Sterilizacijos metodas: gama spinduliuotė**
Priemonės pavadinimas: ACURATE neo2 įterpimo rinkinys

Neaktyvūs neimplantuojami kreipiamieji kateteriai, balioniniai kateteriai, kreipiamosios vielos, įvadai, filtrai ir susijusios priemonės (MDN1203, Is klasė) **Sterilizacijos metodas: etileno oksidu (EtO)**
Priemonės pavadinimas: wireClip sukiklis

Bendrojo naudojimo neaktyvios neimplantuojamos priemonės, naudojamos sveikatos priežiūroje, ir kitos neaktyvios neimplantuojamos priemonės (MDN1213, Is klasė) **Sterilizacijos metodas: gama spinduliuotė**
Priemonės pavadinimas: vienkartinis slankomasis laikiklis variklinei pavarai

Bendrojo naudojimo neaktyvios neimplantuojamos priemonės, naudojamos sveikatos priežiūroje, ir kitos neaktyvios neimplantuojamos priemonės (MDN1214, Is klasė) **Sterilization method:** švitinimas E spinduliais
Priemonės pavadinimas: MDU5 Plus sterilus maišelis **Priemonės pavadinimas:** daugkartinio naudojimo slankomojo laikiklio maišelis

Aktyvios neimplantuojamos vaizdo gavimo priemonės, naudojančios nejonizuojančiąją spinduliuotę (NBOG MDA0202, IIa klasė)
Priemonės pavadinimas: AVVIGO orientavimo sistema II **Priemonės pavadinimas:** AVVIGO+ orientavimo sistema

Neaktyvūs neimplantuojami kreipiamieji kateteriai, balioniniai kateteriai, kreipiamosios vielos, įvadai, filtrai ir susijusios priemonės (MDN1203, IIa klasė)
Priemonės pavadinimas: iSLEEVE įvadų rinkinys

Pirmą kartą išduota: **2022 m. spalio 25 d.** Data: **2024 m. vasario 12 d.** Galioja iki**: 2027 m. spalio 25 d.**

DEKRA Certification B.V. yra notifikuotoji įstaiga, kurios ID Nr. 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem, pašto dėžutė 5185, 6802 ED Arnhem, Nyderlandai
Tel. +31 88 96 83000 www.dekra.nl Įmonės kodas 09085396

Numeris: 3830129CE01

ES kokybės vadybos sistemos sertifikatas

Atitikties vertinimo reglamento 2017/745 dėl medicinos priemonių IX priedo I ir III skyriai

III klasė
Priemonės pavadinimas: ACURATE neo2 aortos vožtuvas
Priemonės pavadinimas: ACURATE neo2 transfemoralinė perdavimo sistema
Priemonės pavadinimas: SYNERGY XD Everolimus išskirianti vainikinių arterijų platinos chromo stentų sistema
Priemonės pavadinimas: SYNERGY MEGATRON Everolimus išskirianti vainikinių arterijų platinos chromo stentų sistema
Priemonės pavadinimas: SYNERGY SHIELD Everolimus išskirianti vainikinių arterijų platinos chromo stentų sistema
Priemonės pavadinimas: Maverick2 Monorail PTCA dilatacijos kateteris
Priemonės pavadinimas: ROTAWIRE pavara ir wireClip sukiklis
Priemonės pavadinimas: Guidezilla II kreipiamasis prailgintas kateteris
Priemonės pavadinimas: Guidezilla II LONG kreipiamasis prailgintas kateteris
Priemonės pavadinimas: SENTINEL smegenų apsauginė sistema
Priemonės pavadinimas: Emerge MONORAIL PTCA dilatacijos kateteris
Priemonės pavadinimas: Emerge Push MONORAIL PTCA dilatacijos kateteris
Priemonės pavadinimas: Emerge OVER-THE-WIRE PTCA dilatacijos kateteris
Priemonės pavadinimas: Emerge Push OVER-THE-WIRE PTCA dilatacijos kateteris
Priemonės pavadinimas: NC Emerge Monorail PTCA dilatacijos kateteris
Priemonės pavadinimas: NC Quantum Apex Monorail PTCA dilatacijos kateteris
Priemonės pavadinimas: Promus PREMIER Everolimus išskirianti vainikinių arterijų platinos chromo stentų sistema
Priemonės pavadinimas: Promus PREMIER Select Everolimus išskirianti vainikinių arterijų platinos chromo stentų sistema
Priemonės pavadinimas: Promus ELITE Everolimus išskirianti vainikinių arterijų platinos chromo stentų sistema
Priemonės pavadinimas: Ultra ICE Plus 9 MHz širdies echoskopijos kateteris
Priemonės pavadinimas: OptiCross vainikinių arterijų vaizdo gavimo kateteris
Priemonės pavadinimas: OptiCross 6 vainikinių arterijų vaizdo gavimo kateteris
Priemonės pavadinimas: OptiCross HD vainikinių arterijų vaizdo gavimo kateteris
Priemonės pavadinimas: OptiCross 6 HD vainikinių arterijų vaizdo gavimo kateteris
Priemonės pavadinimas: Wolverine Coronary Cutting Balloon MONORAIL mikrochirurginės dilatacijos priemonė
Priemonės pavadinimas: MAMBA mikrokateteris
Priemonės pavadinimas: MAMBA Flex mikrokateteris
Priemonės pavadinimas: Agent MONORAIL paklitakseliu dengtas PTCA balioninis kateteris

Pirmą kartą išduota: **2022 m. spalio 25 d.** Data: **2024 m. vasario 12 d.** Galioja iki**: 2027 m. spalio 25 d.**

DEKRA Certification B.V. yra notifikuotoji įstaiga, kurios ID Nr. 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem, pašto dėžutė 5185, 6802 ED Arnhem, Nyderlandai
Tel. +31 88 96 83000 www.dekra.nl Įmonės kodas 09085396

Numeris: 3830129CE01

ES kokybės vadybos sistemos sertifikatas

Atitikties vertinimo reglamento 2017/745 dėl medicinos priemonių IX priedo I ir III skyriai

Šio sertifikato galiojimo sąlygos arba apribojimai:

- Is klasės priemonių atitikties vertinimas, kurį atlieka notifikuotoji įstaiga, yra susijęs tik su sterilių sąlygų sudarymu, užtikrinimu ir palaikymu.

Sertifikato istorija

Techniniuose dokumentuose ir atlikto audito vertinimuose nurodoma, kokių bendrųjų specifikacijų ir darniųjų standartų laikomasi. Juos galima rasti DEKRA Certification B.V. sertifikavimo pranešime. Sertifikavimo pranešime taip pat nurodoma būtina informacija, susijusi su gamintojo kokybės vadybos sistema, įskaitant gamybines patalpas.

Peržiūra	Sertifikato išdavimo data	Sertifikavimo pranešimo nuoroda	Veiksmas
0	2022 m. spalio 25 d.	3812454CN100	Pirmasis išdavimas
1	2022 m. lapkričio 14 d.	3812454CN101	Peržiūra
2	2022 m. lapkričio 30 d.	3812454CN101	Peržiūra
3	2022 m. gruodžio 14 d.	3812454CN101	Peržiūra
4	2023 m. kovo 20 d.	3812454CN102	Peržiūra
5	2023 m. gegužės 3 d.	3812454CN102	Peržiūra
6	2023 m. gegužės 16 d.	3812454CN102	Peržiūra
7	2023 m. birželio 5 d.	3812454CN103	Peržiūra
8	2023 m. birželio 16 d.	3812454CN103	Peržiūra
9	2023 m. rugpjūčio 25 d.	3812454CN103	Peržiūra
10	2023 m. rugsėjo 21 d.	3812454CN104	Peržiūra
11	2023 m. lapkričio 1 d.	3812454CN104	Peržiūra
12	2024 m. sausio 12 d.	3812454CN105	Peržiūra
13	2024 m. sausio 19 d.	3812454CN105	Peržiūra
14	2024 m. vasario 12 d.	3812454CN106	Peržiūra

Pirmą kartą išduota: **2022 m. spalio 25 d.** Data: **2024 m. vasario 12 d.** Galioja iki**: 2027 m. spalio 25 d.**

DEKRA Certification B.V. yra notifikuotoji įstaiga, kurios ID Nr. 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem, pašto dėžutė 5185, 6802 ED Arnhem, Nyderlandai
Tel. +31 88 96 83000 www.dekra.nl Įmonės kodas 09085396

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

07 June 2024

Notified Body Confirmation Letter

Reference: EU2023-607/777352

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

SRN Number (if available): US-MF-000004702

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been

withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

[redacted]

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CLEARSIGN II Amplifier	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Diagnostic Sterile Cables	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Fixed Curve Diagnostic Catheters (diagnostic mapping, pacing, and recording catheters)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 646195, 26 May 2024, 2797
LABSYSTEM PRO EP Recording System	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
LABSYSTEM PRO EP Review Workstation Software (recording and amplifier systems)	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Rhythmia HDx Mapping System	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Steerable Diagnostic Catheters (diagnostic mapping, pacing, and recording catheters)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 646196, 26 May 2024, 2797
Umbilical Cables	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
APDL Drainage Catheter System **Flexima APDL Drainage Catheter System** **Flexima APDL Drainage Catheter System Kit** **Flexima APD Drainage Catheter System** **Flexima APD Drainage Catheter System** **Flexima Biliary Catheter System** **Flexima Biliary Catheter System Kit** **Flexima Biliary Catheter System with Radiopaque Marker** **Flexima Nephrostomy Catheter System** **Flexima Nephrostomy Catheter System Kit** **Flexima QuickStick Drainage Catheter System** **Flexima Ureteral Stent System** **Flexima Ureteral Stent System Kit Percuflex**	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Nephroureteral Stent **Nephroureteral Stent System** **Percuflex Nephroureteral Stent** **Percuflex Ureteral Stent System** **Percuflex Ureteral Stent System Kit** **VanSonnenberg Drainage Catheter System** **vanSonnenberg Sump Sump Catheter System Kit** **VTC Nephrostomy Catheter System** **VTC Nephrostomy Catheter System Kit**			
AccuStick II, AccuStick Needle	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Amplatz Super Stiff Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616368, 26 May 2024, 2797
AngioJet AVX Thrombectomy Set **AngioJet AVX Over-the-Wire Thrombectomy Set**	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
AngioJet Solent Dista Thrombectomy Set	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
ANGIOJET SOLENT omni THROMBECTOMY SET, **AngioJet SOLENT proxi THROMBECTOMY SET**	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
ANGIOJET ULTRA SYSTEM CONSOLE	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
AngioJet Zelante DVT Thrombectomy Set	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Back-up Meier Steerable Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616313, 26 May 2024, 2797
JETSTREAM PVCN100 Console	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
JETSTREAM SC 1.6 Atherectomy Catheter, **JETSTREAM SC 1.85 Atherectomy Catheter,** **(JETSTREAM SC OVER-THE-WIRE Atherectomy Catheter)** **JETSTREAM XC 2.1/3.0 Atherectomy Catheter,**	Class II B	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
JETSTREAM XC 2.4/3.4 Atherectomy Catheter (JETSTREAM XC OVER-THE-WIRE Atherectomy Catheter)			
Mach1 Guide Catheters	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
NVI Connecting Tube	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Percufix Catheter Cuff kit	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Platinum Plus Guidewire, Platinum Plus Glidex Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Stainless Steel Guidewire Floppy Radiopaque Tip Nitinol Guidewire Floppy Radiopaque Tip	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Transend Guidewire with ICE Hyrdophilic Coating	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Transend Guidewires (includes Transend 0.010 Guide Wires, Transend 300 (ES, Floppy) and Transend EX 0.014)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616358, 26 May 2024, 2797
V-14 Control Wire Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
V-18 Control Wire Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
LeVeen CoAcces Electrode System, LeVeen CoAccess Introducer Set, LeVeen Needle Electrode, LeVeen SuperSlim Electrode System, Soloist Single Needle Electrode	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
ChoICE Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
ChoICE Magnet Guidewire	Class III - Non-Impl	ChoICE Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
ChoICE PT Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
ChoICE PT Magnet Guidewire	Class III - Non-Impl	ChoICE PT Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
CrossBoss Catheter	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 617066, 26 May 2024,2797
Expo Angiographic Catheter	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616318, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Fighter Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
Hornet 10 Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
Hornet 14 Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
Hornet Guidewire (Sentai)	Class III - Non-Impl	JUDO 1 Guidewire	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
Impulse Angiographic Catheters	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616317, 26 May 2024, 2797
JUDO 1 Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
JUDO 3 Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
JUDO 6 Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
Luge Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
Luge Magnet Guidewire	Class III - Non-Impl	Luge Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
Mach I Guide Catheter	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616319, 26 May 2024, 2797
Mailman Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
Mailman Magnet Guidewire	Class III - Non-Impl	Mailman Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
Marvel Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
PT Graphix Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
PT Graphix Magnet	Class III - Non-Impl	PT Graphix	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
PT2 Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616304, 26 May 2024, 2797
RunWay Guide Catheter	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616319, 26 May 2024, 2797
Samurai Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
Samurai RC Guidewire (Sentai)	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
Stingray Extension Wire	Class I S	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Stingray Guidewire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 617065, 26 May 2024, 2797
Stingray LP Catheter	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 617065, 26 May 2024, 2797
Stretch Extension Wire	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
WATCHDOG Hemostasis Valve Kit	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
WATCHDOG™ Hemostasis Valve	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Navigator HD Ureteral Access Sheath Set and Navigator Ureteral Access Sheath Set	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Stone Cone Nitinol Urological Retrieval Coil	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
AdVance™ XP Male Sling System	Class III - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Amplatz Type Renal Dilators **Amplatz Type Renal Sheaths** **Amplatz Type Renal Sheath Set** **Amplatz Type Renal Dilator/Sheath Set** **Amplatz Type Graduated Renal Dilatation Set** **8/10 Dilator/Sheath Set** **Clear Renal Sheath**	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
AMS 700 Inflatable Penile Prosthesis	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
AMS 700 Inflatable Penile Prosthesis with IZ	Class III - Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 698551, 26 May 2024, 2797
AMS 700 Accessory Kit	Class IIB- Impl	Not applicable	CE 616288, 26 May 2024, 2797
AMS 800 Artifical Urinary Sphinciter	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
AMS 800 Artifical Urinary Sphinciter with IZ	Class III - Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 698552, 26 May 2024, 2797
AMS Disposal Dilator	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Capio SLIM Suture Capturing Device	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Piranha Ureteroscopic Biopsy Forceps	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Tactra Malleable Penile Prosthesis	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Sensor Nitinol Wire with Hydrophilic Tip	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
ZeroTip Nitinol Stone Retrieval Basket Escape Nitinol Stone Retrieval Basket OptiFlex Nitinol Stone Retrieval Basket Dakota Nitinol Stone Retrieval Basket with OpenSure Handle	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Amplatz Renal Dilator + Set Amplatz Renal Sheath + Set	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Amplatz Super Stiff Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Ureteral Catheter Flexible Tip Open End Ureteral Catheter Set, Ureteral Catheter Open End Ureteral Catheter Set, Ureteral Catheter Pigtail Ureteral Catheter Set	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Ureteral Catheter Open End Ureteral Catheter, Ureteral Catheter Cone Tip Ureteral Catheter, Ureteral Catheter Olive Tip Ureteral Catheter, Ureteral Catheter Spiral Tip Ureteral Catheter, Ureteral Catheter Wedge Tip Ureteral Catheter, Ureteral Catheter Angled Tip Ureteral Catheter Dual Lumen Ureteral Catheter Open End Ureteral Axxcess Catheter	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Urolok™ II Adaptor	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Zebra Guidewires	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
SAPS CF Single Action Pumping System Continuous Flow Single Action Pumping System (irrigation)	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Nottingham One-Step Hydrogel Coated Ureteral Dilator **Ureteral Dilatation System**	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Gemini Paired Wire Helical Stone Retrieval Basket **Segura Hemisphere Stone Retrieval Basket**	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
TLA Introducer Needle and Sheath Set **NaviGuide Percutaneous Access Needles** **Percutaneous Access Needle** **Percutaneous Access Needle with Echogenic Tip**	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Captiflex Single-Use Polypectomy Snare	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Captivator II Single-Use Polypectomy Snare	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Captivator Single-Use Polypectomy Snare	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Expect Pulmonary Adaptor	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Gold Probe Bipolar Electrohemostasis Catheters	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Injection Gold Probe Bipolar Electrohemostasis Catheters	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Rotatable Snare	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Sensation™ Short Throw Single-Use Polypectomy Snare	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Speedband™ Superview Super 7 Band Ligator	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
SpyBite Max Biopsy Forceps	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
SpyGlass Retrieval Basket	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
SpyGlass Retrieval Snare	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Ultratome XL Triple Lumen Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
AutoCap RX Integrated Biopsy Cap Locking device	Class I S	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Acquire Pulmonary Endobronchial Ultrasound Fine Needle Biopsy Device	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Captivator™ COLD Single-Use Polypectomy Snare	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Captivator™ EMR device	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Cellebrity Cytology Brushes	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Contour ERCP Cannula	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
CoreDx Pulmonary Mini-Forceps Biopsy Forceps	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Dreamtome RX Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Dreamwire High Performance Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
eXcelon™ Transbronchial Aspiration Needle	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Expect™ Endoscopic Ultrasound Aspiration Needle	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Expect™ Slimline Endoscopic Ultrasound Aspiration Needle	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Hydra Irrigation Tubing System	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Hydra Jagwire High Performance Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Hydra Water Bottle Cap System	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Hydratome RX Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Interject Injection Therapy Needle Catheter	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Jagtail High Performance Guidewire Extension	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Jagtome Revolution RX Cannulating Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Jagwire Revolution High Performance Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
MicroKnife XL Triple Lumen Needle Knife	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Orca Air/Water and Suction Valves	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
OrcaPod Single use Air/Water, Suction and Biopsy Valves set	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Pneumatic Inflator	Class I M	Not applicable	CE 616288, 26 May 2024, 2797
Pulmonary Jagwire Pulmonary Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Radial Jaw 4 Single-use Biopsy Forceps	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Radial Jaw 4 Single-use Biopsy Forceps (Pulmonary)	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Radial Jaw 4 Single-use Hot Biopsy Forceps	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Rapid Exchange XL Cannula	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Rapid Refill Continuous Injection System	Class I S/M	Not applicable	CE 616288, 26 May 2024, 2797
RescueNet Retrieval Device	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
RX Cytology Brush	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
RX ERCP Cannula	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
RX Locking Device and Biopsy Cap	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
RX Needle Knife XL Triple Lumen Needle Knife	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Tandem XL Triple-Lumen ERCP Cannula	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Trapezoid RX Wireguided Retrieval Basket	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
TRUEtome Cannulating Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
TRUEtome Dreamwire Cannulating Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TRUEtome Hydra Cannulating Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
TRUEtome Jag Cannulating Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
TRUEtome Revolution Cannulating Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Zero Tip™ Airway Retrieval Basket	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Amplatz Super Stiff Guidewire	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Autotome RX Cannulating Sphincterotome	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Hydra Disposable Auxiliary Water Jet Connector	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
ACUITY Mailman Venous Guide Wire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
ACUITY Cutter	Class I s	Not applicable	CE 616288, 26 May 2024, 2797
ACUITY Whisper View Guide Wire	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
AngioJet Power Pulse Kit	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/03/01	Initial issue
2024/03/12	Amended - Administrative update to correct typographical error in the MDR Classification for Rhythmia HDx Mapping System from IIa to IIb and added DE MDD certificates missing for IntellaMap, Amplatz Super Stiff, Back-up Meier, AdVance™ XP, AMS 700, AMS 800, ACUITY Mailman.
2024/06/04	Amended: - Added Class IIa AngioJet Power Pulse Kit - Removed Class III IntellaMap Orion High Resolution Mapping Catheter - Removed Orbiter PV Mapping Diagnostic Catheter from the Steerable Diagnostic Catheters - Removed Tango from the Fixed Curve Diagnostic Catheters - Removed Class IIa Jagwire High Performance Extendable Guidewire, Jagwire High Performance Guidewire, Jagtome RX Cannulating Sphincterotome - Removed Class IIa SpyBite Single-use Biopsy Forceps
2024/06/06	Amended: Removed Class II B Rhythmia Mapping System

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
JAV

2024 m. birželio 7 d.

Notifikuotosios įstaigos patvirtinimo raštas

Nuoroda: EU2023-607/777352

Visiems suinteresuotiesiems,

oficialios paraiškos, rašytinio susitarimo ir tinkamos priežiūros pagal Reglamentą ES 2023/607, kuriuo iš dalies keičiami reglamentai (ES) 2017/745 ir (ES) 2017/746, kiek tai susiję su pereinamojo laikotarpio nuostatomis dėl tam tikrų medicinos priemonių ir *in vitro* diagnostikos medicinos priemonių, būsenos patvirtinimas.

Šiuo laišku patvirtinama, kad „**BSI Group The Netherlands B.V.**“, notifikuotoji įstaiga (toliau – NĮ), įgaliota pagal Reglamentą (ES) 2017/745 (toliau – MPR) ir identifikuojama NANDO numeriu **2797**, gavo oficialią paraišką pagal MPR VII priedo 4.3 skirsnio pirmą punktą ir sudarė rašytinį susitarimą (2021 m. kovo 10 d.) pagal MPR VII priedo 4.3 skirsnio antrą punktą su toliau nurodytu gamintoju:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
JAV

SRN numeris (jei yra): US-MF-000004702

Priemonės, dėl kurių pateikta pirmiau minėta oficiali paraiška ir sudarytas rašytinis susitarimas, nurodytos toliau pateiktose lentelėse. Lentelėje Nr. 1 yra nurodytos priemonės, dėl kurių buvo gauta MPR paraiška, sudarytas rašytinis susitarimas ir dėl kurių tinkamos priežiūros pagal taikytiną direktyvą yra atsakinga NĮ. Lentelėje Nr. 2 yra nurodytos priemonės, dėl kurių buvo gauta MPR paraiška ir sudarytas rašytinis susitarimas, tačiau NĮ dar neprisiėmė atsakomybės už tinkamą šių priemonių priežiūrą pagal taikytiną direktyvą.

Priemonių, kurioms taikomi pagal Direktyvą 90/385/EEB (toliau – AIMDD) arba Direktyvą 93/42/EEB (toliau – MPD) išduoti sertifikatai, kurių galiojimas baigėsi po 2021 m. gegužės 26 d. ir iki 2023 m. kovo 20

d., tačiau nebuvo atšaukti, atveju šiuo raštu taip pat patvirtinama, kad gamintojas pasirašė rašytinį susitarimą pagal MPR iki MPD / AIMDD sertifikato galiojimo pabaigos datos; arba pateikė įrodymų, kad valstybės narės kompetentinga institucija iki 2023 m. kovo 20 d. atitinkamoms priemonėms pritaikė nuo taikytinos atitikties įvertinimo procedūros nukrypti leidžiančią nuostatą arba išimtį atitinkamai pagal MPR 59 straipsnio 1 dalį arba MPR 97 straipsnio 1 dalį.

Toliau pateikiami pereinamojo laikotarpio terminai, taikomi šiame laiške nurodytoms priemonėms, jei gamintojas ir toliau laikosi kitų MPR 120.3c straipsnyje (su pakeitimais, padarytais (ES) 2023/607) nurodytų sąlygų:

- 2026 m. gegužės 26 d. – III klasės pagal užsakymą gaminamiems implantuojamiems prietaisams;
- 2027 m. gruodžio 31 d. – III klasės priemonėms ir IIb klasės implantuojamiems prietaisams, išskyrus nusistovėjusias technologijas (*angl.* Well-established technologies, WET) (WET – siūlai, kabės, dantų plombos, dantų breketai, dantų vainikėliai, sraigtai, pleištai, plokštelės, vielos, smeigtukai, spaustukai ir jungtys);
- 2028 m. gruodžio 31 d. – kitoms IIb klasės priemonėms, IIa klasės, I klasės priemonėms, kurios į rinką pateikiamos sterilios būklės arba atlieka matavimo funkciją;
- 2028 m. gruodžio 31 d. – priemonėms, dėl kurių pagal MPD nebūtinas notifikuotosios įstaigos dalyvavimas, tačiau pagal MPR jis būtinas (pvz., I klasės priemonėms, kurios laikomos daugkartinio naudojimo chirurginiais instrumentais).

„BSI Group The Netherlands B.V.“ vardu,

[redacted]

Graeme Tunbridge
Vyresnysis pirmininko pavaduotojas, Medicinos priemonių skyrius

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

Your ref. NoC 2023-080, 2024-034
Our ref. MED/24-3835256 Rev3
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E-mail medical.nl@dekra.com

26 March 2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement (dated 10 March 2021) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
SRN: US-MF-000004702

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2

identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

[redacted]

Amy Gravley
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Electrophysiology (EP) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Dx Sterile Cables - DEKRA	Class I S	Not applicable	3812454CE01
Rx Sterile Cables - DEKRA	Class I S	Not applicable	3812454CE01
Blazer Dx-20 Diagnostic Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE15
Blazer II HTD Temperature Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer II Temperature Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer II XP Temperature Ablation Catheter & XP HTD	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer Prime XP Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Blazer Prime HTD Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav MiFi Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE37
IntellaNav MiFi XP Temperature Ablation Catheters	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav ST Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaNav StablePoint Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
IntellaTip MiFi Open-Irrigated Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE37
IntellaTip MiFi XP Temperature Ablation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE14
Irrigation Tubing Set	Class II A	Not applicable	3812454CE01
MetriQ Irrigation Tubing Set	Class II A	Not applicable	3812454CE01

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MetriQ Pump	Class II B	Not applicable	3812454CE01
Polaris X Steerable Diagnostic Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE15

Peripheral Interventions (PI) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
2D Helical-35 Fibered Platinum Coil	Class II B - Impl	Not applicable	3812454CE01
Athletis	Class II A	Not applicable	3812454CE01
Berenstein & Standard Occlusion Balloon Catheter (IIB)	Class II B	Not applicable	3812454CE01
Carotid Wallstent Monorail Carotid Endoprostesis	Class III - Impl	Not applicable	3812454CE01 3812454DE28
Charger PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Coil Pusher-16	Class II A	Not applicable	3812454CE01
Contour Embolization Particles	Class II B - Impl	Not applicable	3812454CE01
Coyote Balloon Dilatation Catheters MR & OTW	Class II A	Not applicable	3812454CE01
Coyote ES Monorail PTA Catheter	Class II A	Not applicable	3812454CE01
Coyote ES Over-the-Wire PTA Catheter	Class II A	Not applicable	3812454CE01
Direxion Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion HI-FLO Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion Fathom -16 System Pre-Loaded Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion Transend-14 System Pre-Loaded Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion HI-FLO Fathom-16 System Pre-Loaded Torqueable Microcatheter	Class II B	Not applicable	3812454CE01
Direxion HI-FLO Transend-18 System Pre-Loaded Torqueable	Class II B	Not applicable	3812454CE01

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Microcatheter			
ELUVIA Over-The-Wire Drug-Eluting Vascular Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE38
Epic Over the WireSelf-Expanding Nitinol Vascular Stent with Delivery System	Class II B - Impl	Not applicable	3812454CE01
Equalizer Occlusion Balloon	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE11
Express Vascular LD Premounted Stent System	Class II B - Impl	Not applicable	3812454CE01
Express Vascular SD Premounted Stent System	Class II B - Impl	Not applicable	3812454CE01
Fathom 016 Steerable Guidewire	Class II A	Not applicable	3812454CE01
Fathom-14 Steerable Guidewire	Class II A	Not applicable	3812454CE01
Fibered Platinum Coils : VortXTM - 18 and VortXTM Diamond-18 Fibered Platinum Coils Complex Helical-18, Figure 8-18, Multi-Loop-18, straight-18 Fibered Platinum Coils	Class II B - Impl	Not applicable	3812454CE01
FloSwitch HP High Pressure Flow Control Device	Class II A	Not applicable	3812454CE01
Gateway PTA Balloon Catheter (Gateway)	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE10
Guider Softip XF Guide Catheter 5FR - 6FR - 7FR - 8FR	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE02
IDC Interlocking Detachable Coils	Class II B - Impl	Not applicable	3812454CE01
Innova Over-The-Wire Self-Expanding Stent System	Class II B - Impl	Not applicable	3812454CE01
Interlock - 35 Fibered IDC Occlusion System	Class II B - Impl	Not applicable	3812454CE01
Interlock Fibered IDC Occlusion System	Class II B - Impl	Not applicable	3812454CE01
Mustang PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
OptiCross 35	Class II A	Not applicable	3812454CE01
Peripheral Cutting Balloon (2cm Peripheral Cutting Balloon)	Class II A	Not applicable	3812454CE01

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Microsurgical Dilatation Device			
Renegade Fiber Braided Microcatheter	Class II B	Not applicable	3812454CE01
Renegade Hi-Flo Fathom System	Class II B	Not applicable	3812454CE01
Renegade Hi-Flo Microcatheter Kits	Class II B	Not applicable	3812454CE01
Renegade Hi-Flo Microcatheter.	Class II B	Not applicable	3812454CE01
Renegade STC-18 Microcatheter	Class II B	Not applicable	3812454CE01
Rubicon Support Catheter 14, 18 & 35	Class II A	Not applicable	3812454CE01
Sterling Monorail PTA Balloon dilatation catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE10
Sterling Over-The-Wire PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Sterling SL Monorail PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Sterling SL Over-The-Wire PTA Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Trueselect	Class II B	Not applicable	3812454CE01
VortX-35 Fibered Platinum Coil	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Fully Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Fully Covered Stent System RMV	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Partially Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary Transhepatic Uncovered Stent System	Class II B - Impl	Not applicable	3812454CE01
Wallstent RP Endoprosthesis	Class II B - Impl	Not applicable	3812454CE01
Wallstent-Uni Endoprosthesis IIb	Class II B - Impl	Not applicable	3812454CE01
Wallstent-Uni Endoprosthesis III	Class III - Impl	Not applicable	3812454CE01 3812454DE25
XXL Balloon Dilatation Catheter (Vascular)	Class II A	Not applicable	3812454CE01
EMBOZENE Color-Advanced Microspheres	Class II B - Impl	Not applicable	3812454CE01
TANDEM Microspheres	Class III	Not applicable	3812454CE01 3812454DE44

Interventional Cardiology (IC) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
OptiCross 6 Coronary Imaging Catheter & OptiCross 6 HD Coronary Imaging Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE18
OptiCross Coronary Imaging Catheter & OptiCross HD Coronary Imaging Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE18
Comet II Pressure Guidewire	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE39
Comet Pressure Guidewire	Class III - Non-Impl	Comet II Pressure Guidewire	3812454CE01 3812454DE39
Disposable Pullback Sled	Class I S	Not applicable	3812454CE01
Emerge MONORAIL PTCA Dilatation Catheter Emerge Push MONORAIL PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE23
Emerge OVER-THE-WIRE PTCA Dilatation Catheter Emerge Push OVER-THE-WIRE PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE23
Encore 26 Advantage Kit	Class II A	Not applicable	3812454CE01
Encore 26 Inflation Device	Class I S/M	Not applicable	3812454CE01
Fluid Dock	Class I S	Not applicable	3812454CE01
GateWay Plus Y-Adapter	Class II A	Not applicable	3812454CE01
Guidezilla II Guide Extension Catheter	Class III - Non-Impl	Not applicable	3812454CE01
Guidezilla II LONG Guide Extension Catheter	Class III - Non-Impl	Not applicable	3812454CE01
Mamba and Mamba Flex Microcatheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE42
Maverick 2 Monorail PTCA	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE20
MDU5 PLUS Sterile Bag	Class I S	Not applicable	3812454CE01
NC Emerge PTCA Dilatation Catheter (MONORAIL)	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE34
NC Quantum Apex MONORAIL PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE12

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
NC Quantum Apex OVER-THE-WIRE PTCA Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE12
OptiCross 18 30 MHz Peripheral Imaging Catheter	Class II A	Not applicable	3812454CE01
PROMUS Elite Monorail Everolimus-Eluting Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE43
Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE06
Promus PREMIER Select MONORAIL Everolimus-Eluting Platinum Chromium Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE41
Rotablator Rotational Angioplasty System: Console	Class II A	Not applicable	3812454CE01
Rotablator RotaWire Guidewire with wireClip Torquer	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE24
RotaLink Advancer Catheter Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
RotaLink Burr Exchangeable Burr Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
RotaLink Plus Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
ROTAPRO Rotational Angioplasty System: Console	Class II A	Not applicable	3812454CE01
ROTAPRO Advancer Burr Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
ROTAPRO Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE26
Synergy MEGATRON MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE32
Synergy XD MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE46

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Threader Monorail Micro-Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE33
Threader Over the Wire Micro-Dilatation Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE33
Ultra ICE Plus 9 IntraCardiac Echo Catheter	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE18
WireClip Torquer	Class I S	Not applicable	3812454CE01
Wolverine Coronary Cutting Balloon MONORAIL Microsurgical Dilatation Device	Class III - Non-Impl	Not applicable	3812454CE01 3812454DE40
SYNERGY MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	Class III - Impl	Synergy XD Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE32

Urology and Pelvic Health (Uro) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
UroMax Ultra Balloon Dilation Catheter	Class II A	Not applicable	3812454CE01
Encore 26 Inflation Device	Class I S/M	Not applicable	3812454CE01
Gateway Advantage Y-Adapter	Class II A	Not applicable	3812454CE01
Nephromax High Pressure Nephrostomy Balloon Catheter	Class II A	Not applicable	3812454CE01
Occluder Occlusion Balloon Catheter	Class II A	Not applicable	3812454CE01
SpaceOAR	Class III - Impl	Not applicable	3812454CE01 3812454DE47
SpaceOAR Vue	Class III - Imp	Not applicable	3812454CE01 3812454DE47

Endoscopy (Endo) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Agile Esophageal Partially Covered Stent System, Agile Esophageal Fully Covered Stent System, Agile Esophageal Fully Covered removable (RMV) Stent System, Agile Esophageal Partially Covered Over-the-wire (OTW) Stent System, Agile Esophageal Fully Covered Over-the-wire (OTW) Stent System, Agile Esophageal Fully Covered removable (RMV) Over-the-wire (OTW) Stent System	Class II B - Impl	Not applicable	3812454CE01
Alliance II Integrated Inflation System (60ml Syringe/Gauge assembly)	Class I S/M	Not applicable	3812454CE01
Hurricane Rapid Exchange Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE RX Biliary Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE Wireguided Balloon Dilatation Catheter	Class II B - Impl	Not applicable	3812454CE01
CRE Fixed Wire Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE PRO Wireguided Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
CRE Pulmonary Balloon Dilatation Catheter	Class II A	Not applicable	3812454CE01
Encore 26 Inflation device	Class I S	Not applicable	3812454CE01
Extractor Pro Retrieval Balloon Catheter (RX, RX-S, XL)	Class I S/M	Not applicable	3812454CE01
Resolution 360 Clip Resolution Clip Device	Class I S	Not applicable	3812454CE01
Resolution 360 Ultra Clip	Class II B - Impl	Not applicable	3812454CE01
Rigiflex II Single Use Achalasia Balloon Dilator	Class I S	Not applicable	3812454CE01
Ultraflex Esophageal Stent System	Class II B - Impl	Not applicable	3812454CE01

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
(Covered & Uncovered) - Large Esophageal & Esophageal NG			
Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Non sterile	Class II B - Impl	Not applicable	3812454CE01
Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Sterile	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Fully Covered	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Fully Covered RMV	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Partially Covered	Class II B - Impl	Not applicable	3812454CE01
WallFlex Biliary RX Stent System Uncovered	Class II B - Impl	Not applicable	3812454CE01
WallFlex Enteral Stent With Anchor lock delivery System (Colonic)	Class II B - Impl	Not applicable	3812454CE01
WallFlex Enteral Stent With Anchor lock delivery System (Duodenal)	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Fully Covered RMV Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Fully Covered RMV Stent System Longer Loop	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Fully Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Esophageal Partially Covered Stent System	Class II B - Impl	Not applicable	3812454CE01
WallFlex Soft Enteral Stent With Anchor lock delivery System (Colonic)	Class II B - Impl	Not applicable	3812454CE01
WallFlex Soft Enteral Stent With Anchor lock delivery System (Duodenal)	Class II B - Impl	Not applicable	3812454CE01

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Interventional Cardiology (IC) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
iSLEEVE Introducer Set	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
Sentinel Cerebral Protection System	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 717743, 26 May 2024, 2797

Urology and Pelvic Health (Uro) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Gen 1 - Rezum System and Delivery Device Kit - Console	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Gen 1 - Rezum System and Delivery Device Kit - SUD	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Nephrostomy Catheter and Sets Percuflex Locking Loop Nephrostomy Catheter Percuflex Combination Stent/Nephrostomy Catheter Percuflex Locking Loop Catheter with Stent Percuflex Locking Loop All Purpose Drainage Catheter with Fader Tip Percuflex Locking Loop	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Nephrostomy Catheter Kit Jinro Pigtail Nephrostomy Catheter Kit Jinro Pigtail Nephrostomy Catheter Jinro Pigtail Nephrostomy Catheter Replacement Kit			
Percuflex Urinary Diversion Stent Set	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Percuflex™ Ureteral Stent Percuflex™ Plus Ureteral Stent Contour™ Ureteral Stent Contour VL™ Variable Length Ureteral Stent Contour VL™ Variable Length Ureteral Stent Set Contour VL™ SureDrive™ Steerable Ureteral Stent Set Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set Polaris™ Ultra Ureteral Stent Polaris™ Loop Ureteral Stent Tria Firm Ureteral Stent Tria Soft Ureteral Stent	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Auriga™ XL 4007 Laser System			
Auriga™ 30 Laser System	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
GreenLight XPS Laser System	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
LightTrail Single Use & Reusable Use Laser Fibers	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
LightTrail TracTip Single Use Laser Fibers	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
LithoVue Empower Retrieval	Class II A	Not applicable	CE 616288, 26 May

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Deployment Device			2024, 2797
Lithovue System	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
Moxy Fiber GreenLight HPS Fiber GreenLight Fiber	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Endoscopy (Endo) Products:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Advanix Biliary Biliary Stent with NaviFlex RX Delivery System, Advanix Biliary Biliary Stent, Stent Delivery System, Biliary Stent Introducer	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Flexima Biliary Biliary Stent with Delivery System	Class II B - Impl	Not applicable	Flexima Biliary Biliary Stent with Delivery System
RX Biliary Biliary Stent with RX Delivery System	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
Advanix Pancreatic Stent Kit, Advanix Pancreatic Stent, Naviflex RX Delivery System Pancreatic Stent Delivery System, Naviflex RX Pusher	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
AXIOS Stent and Delivery System	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
EXALT MODEL B SINGLE-USE BRONCHOSCOPE	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
EXALT Model D Single-Use	Class II A	Not applicable	CE 616288, 26 May

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Duodenoscope			2024, 2797
Habib EndoHPB Radiofrequency Ablation Catheter	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
Hot Axios Stent and Electrocautery-Enhanced Delivery System	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
SpyGlass Discover Digital Catheter	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
SpyScope DS Access and Delivery Catheter & SpyScope DS II Access and Delivery Catheter	Class II A	Not applicable	CE 616288, 26 May 2024, 2797

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2024/01/30	3812454CN104.1	Initial issue
2024/02/06	NA	Addition of Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
2024/02/20	N/A	Update to include EMBOZENE Color-Advanced Microspheres and TANDEM Microspheres as per MDR application received (NoC 2024-034) in the Peripheral Interventions (PI) Products table.
2024/03/25	N/A	Update to correct Tandem Microspheres to Class III. Update Embozene to correct certificate reference.

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2024 m. kovo 26 d.

Tema: Notifikuotosios įstaigos patvirtinimo raštas

Visiems suinteresuotiesiems,

oficialios paraiškos, rašytinio susitarimo ir tinkamos priežiūros pagal Reglamentą ES 2023/607, kuriuo iš dalies keičiami reglamentai (ES) 2017/745 ir (ES) 2017/746, kiek tai susiję su pereinamojo laikotarpio nuostatomis dėl tam tikrų medicinos priemonių ir *in vitro* diagnostikos medicinos priemonių, būsenos patvirtinimas.

Šiuo laišku patvirtinama, kad „DEKRA Certification B.V.“, notifikuotoji įstaiga (toliau – NĮ), įgaliota pagal Reglamentą (ES) 2017/745 (toliau – MPR) ir identifikuojama NANDO numeriu 0344, gavo oficialią paraišką pagal MPR VII priedo 4.3 skirsnio pirmą punktą ir sudarė rašytinį susitarimą (2021 m. kovo 10 d.) pagal MPR VII priedo 4.3 skirsnio antrą punktą su toliau nurodytu gamintoju:

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JAV
SRN: US-MF-000004702

Priemonės, dėl kurių pateikta pirmiau minėta oficiali paraiška ir sudarytas rašytinis susitarimas, nurodytos toliau pateiktose lentelėse. Lentelėje Nr. 1 yra nurodytos priemonės, dėl kurių buvo gauta MPR paraiška, sudarytas rašytinis susitarimas ir dėl kurių tinkamos priežiūros pagal taikytiną direktyvą yra atsakinga NĮ.

Lentelėje Nr. 2 yra nurodytos priemonės, dėl kurių buvo gauta MPR paraiška ir sudarytas rašytinis susitarimas, tačiau NĮ dar neprisiėmė atsakomybės už tinkamą šių priemonių priežiūrą pagal taikytiną direktyvą.

Priemonių, kurioms taikomi pagal Direktyvą 90/385/EEB (toliau – AIMDD) arba Direktyvą 93/42/EEB (toliau – MPD) išduoti sertifikatai, kurių galiojimas baigėsi po 2021 m. gegužės 26 d. ir iki 2023 m. kovo 20 d., tačiau nebuvo atšaukti, atveju šiuo raštu taip pat patvirtinama, kad gamintojas pasirašė rašytinį susitarimą pagal MPR iki MPD / AIMDD sertifikato galiojimo pabaigos datos; arba pateikė įrodymų, kad valstybės narės kompetentinga institucija iki 2023 m. kovo 20 d. atitinkamoms priemonėms pritaikė nuo taikytinos atitikties įvertinimo procedūros nukrypti leidžiančią nuostatą arba išimtį atitinkamai pagal MPR 59 straipsnio 1 dalį arba MPR 97 straipsnio 1 dalį.

Toliau pateikiami pereinamojo laikotarpio terminai, taikomi šiame laiške nurodytoms priemonėms, jei gamintojas ir toliau laikosi kitų MPR 120.3c straipsnyje (su pakeitimais, padarytais (ES) 2023/607) nurodytų sąlygų:

- 2026 m. gegužės 26 d. – III klasės pagal užsakymą gaminamiems implantuojamiems prietaisams;
- 2027 m. gruodžio 31 d. – III klasės priemonėms ir IIb klasės implantuojamiems prietaisams, išskyrus nusistovėjusias technologijas (*angl.* Well-established technologies, WET) (WET – siūlai, kabės, dantų plombos, dantų breketai, dantų vainikėliai, sraigtai, pleištai, plokštelės, vielos, smeigtukai, spaustukai ir jungtys);
- 2028 m. gruodžio 31 d. – kitoms IIb klasės priemonėms, IIa klasės, I klasės priemonėms, kurios į rinką pateikiamos sterilios būklės arba atlieka matavimo funkciją;
- 2028 m. gruodžio 31 d. – priemonėms, dėl kurių pagal MPD nebūtinas notifikuotosios įstaigos dalyvavimas, tačiau pagal MPR jis būtinas (pvz., I klasės priemonėms, kurios laikomos daugkartinio naudojimo chirurginiais instrumentais).

[redacted]

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Holds Certificate Number: **MD 670368**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

[redacted]

Original Registration Date: 2017-05-08
Latest Revision Date: 2023-08-29

Effective Date: 2023-09-02
Expiry Date: 2026-09-01

...making excellence a habit.™

Certificate No: **MD 670368**

Registered Scope:

The design, development, manufacture and distribution of devices in the areas of Cardiovascular (including Cardiovascular Interventions), Peripheral (including Peripheral Interventions), Electrosurgical Applications (including Electrophysiology), Gastroenterology, Nephrology, Neurology (including Neurovascular), Gynecology, Urology, Radiology, Endoscopy, Biliary, General Surgery (including Minimally Invasive Surgical Procedures), and Embolic Protection. Manufacture activities associated with radio frequency and cryo ablation devices and accessories. Products include: Biliary stents, cardiovascular stents, ureteral stents, pancreatic stents; balloon catheters, angiographic catheters, microcatheters, drainage catheters, introducer catheters, urological catheters, percutaneous catheters, ablation catheters, and guide catheters; biliary devices, surgical mesh, electrosurgical instruments and generators, software for generators, retrieval devices, feeding devices, cannulas, electrodes, endoscopes, examination gloves, irrigation/drainage devices and sets, Fluid circulations pumps, fluid administration, filling and infusion devices, inflators, ligators, dilators, connecting tubes, access sheaths, tubing sets; adaptors; left atrial appendage (LAA) closure devices and accessory devices; percutaneous access needles, aspiration needles, injection needles, introducer needles, endotherapy electrode system, fiber optic laser delivery devices; radiofrequency and cryo ablation system, systems and accessory devices; sutures and suturing devices, syringes, vascular introducers, nephrostomy devices, guidewires, biopsy devices, polypectomy devices, hemostasis devices, torque devices, cuff kits, endoscopic valves, endoscope channel support kits, biopsy caps, locking devices, bladder evacuators, sphincterotomes, embolic protection systems, and embolization coils, ultrasound imaging catheters, retrieval sheaths, diagnostic software and recording systems, diagnostic mapping, pacing and recording catheters inclusive of accessory devices, pericardiocentesis kits; cables. Minimally invasive tissue and thrombus removal devices, atherectomy angioplasty devices, electrophysiology recording and mapping systems, including refurbishment, and software inclusive of accessory devices. Ultrasound Imaging Systems.

External instrumentation for implantable cardiac monitors, implantable cardiac pulse generators and implantable cardioverter defibrillators including implantable cardiac pacing and defibrillation leads. Design, development, manufacture, and sterilization of penile prosthesis and associated accessories, implants for incontinence and associated accessories and surgical tools. Manufacture of medical laser systems and accessories.

Manufacture and service of medical device electronic systems associated with diagnostics, monitoring and therapy.

The installation of peripheral intervention systems (including minimally invasive tissue and thrombus removal devices) and ultrasound imaging systems and service (software upgrades and updates) of capital equipment.

Manufacture medical device components and subassemblies for gastrointestinal, endoscopy and biliary medical devices.

Original Registration Date: 2017-05-08

Effective Date: 2023-09-02

Latest Revision Date: 2023-08-29

Expiry Date: 2026-09-01

Certificate No: **MD 670368**

Location	Registered Activities
Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica	Design, development, manufacture of devices in the areas of Cardiovascular (including Cardiovascular Interventions), Peripheral (including Peripheral Interventions), Electrosurgical Applications (including Electrophysiology), Gastroenterology, Nephrology, Neurology (Including Neurovascular), Gynecology, Urology, Endoscopy, Biliary and General Surgery (including Minimally Invasive Surgical Procedures). These products include Guidewires, Diagnostic mapping, pacing and recording catheters inclusive of accessory devices, and embolic protection systems. Manufacture of cardiac diagnosis, mapping and ablation catheters, guidewires, torque devices for use with atherectomy and minimally invasive tissue and thrombus removal devices; pericardiocentesis kits. Design and development of inflators, hemostasis devices, torque devices, introducer needles, and embolization coils. The Design and development of balloon catheters, Angiographic Catheters, Microcatheters, Ureteral Stents, Drainage Catheters, Urological Catheters, Connecting Tubes, and Introducer Needles
Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela Costa Rica	Manufacture of devices in the areas of Peripheral (including Peripheral Interventions), Cardiovascular (including Cardiovascular Interventions), Electrosurgical Applications (including Electrophysiology), Gastroenterology, Nephrology, Gynecology, Urology, Endoscopy, Biliary, General Surgery (including Minimally Invasive Surgical Procedures) and Embolic Protection. Manufacture activities associated with radio frequency ablation devices and accessories. Products include: biliary stents, ureteral stents, drainage catheters, introducer catheters, urological catheters, percutaneous catheters, biliary devices, ligators, adaptors, percutaneous access needles, injection needles, sutures and suturing devices, nephrostomy devices, guidewires, biopsy devices, polypectomy devices, hemostasis devices, torque devices, sphincterotomes, embolic protection systems, fluid filling devices, ultrasound imaging catheters, electrodes, cannulas, retrieval devices, retrieval sheaths, and endoscopes. Manufacture of intravascular recanalization systems.
Boston Scientific Corporation 300 Boston Scientific Way Marlborough Massachusetts 01752 USA	Administrative Activities.

Original Registration Date: 2017-05-08

Effective Date: 2023-09-02

Latest Revision Date: 2023-08-29

Expiry Date: 2026-09-01

Certificate No: **MD 670368**

Location	Registered Activities
Boston Scientific Corporation 780 Brookside Drive Spencer Indiana 47460 USA	Manufacture of devices in the areas of Peripheral (including Peripheral Interventions), Electrosurgical Applications (including Electrophysiology), Gastroenterology, Nephrology, Gynecology, Urology, Radiology, Endoscopy, Biliary, General Surgery (including Minimally Invasive Surgical Procedures). These products include: Surgical meshes, biliary stents, ureteral stents, pancreatic stents; drainage catheters, introducer catheters, urological catheters, percutaneous catheters and guide catheters; biliary devices, retrieval devices, feeding devices, cannulas, endoscopes, examination gloves, irrigation/drainage devices and sets, fluid administration and infusion devices, inflators, ligators, dilators, connecting tubes, access sheaths adaptors; percutaneous access needles, aspiration needles, injection needles, introducer needles, endotherapy electrode system; syringes, vascular introducers, nephrostomy devices, guidewires, biopsy devices, polypectomy devices, hemostasis devices, torque devices, cuff kits, biopsy caps, locking devices, bladder evacuators and sphincterotomes. The manufacture of medical device accessories for use with implantable cardioverter defibrillators, including implantable cardiac defibrillation leads.

Original Registration Date: 2017-05-08
Effective Date: 2023-09-02
Latest Revision Date: 2023-08-29
Expiry Date: 2026-09-01

Certificate No: **MD 670368**

Location	Registered Activities
Boston Scientific Ltd. 2 Paget Rd Unit #2 Brampton Ontario L6T 5G3 Canada	The manufacture (labeling) and distribution of devices in the areas of cardiovascular (including Cardiovascular Interventions), Peripheral (including Peripheral Interventions), Electrosurgical Applications (including Electrophysiology), Gastroenterology, Nephrology, Neurology (including Neurovascular), Gynecology, Urology, Radiology, Endoscopy, Biliary, General Surgery (including Minimally Invasive Surgical Procedures), and Embolic Protection. These products include: Biliary stents, cardiovascular stents, ureteral stents, pancreatic stents, angiographic catheters, drainage catheters, introducer catheters, urological catheters, percutaneous catheters, ablation catheters, and guide catheters, biliary devices, electrosurgical instruments and generators, software for generators, retrieval devices, feeding devices, cannulas, endoscopes, examination gloves, irrigation/drainage devices and sets, Fluid circulations pumps, fluid administration, filling and infusion devices, inflators, ligators, dilators, connecting tubes, access sheaths, tubing sets, adaptors, left atrial appendage (LAA) closure devices and accessory devices, percutaneous access needles, aspiration needles, injection needles, introducer needles, endotherapy electrode system, radiofrequency ablation system, systems and accessory devices, surgical meshes, sutures and suturing devices, syringes, vascular introducers, nephrostomy devices, guidewires, biopsy devices, polypectomy devices, hemostasis devices, torque devices, endoscopic valves, endoscope channel support kits, cuff kits, biopsy caps, locking devices, bladder evacuators, sphincterotomes, embolic protection systems, ultrasound imaging catheters, retrieval sheaths, diagnostic software and recording systems, diagnostic mapping, pacing and recording catheters inclusive of accessory devices, pericardiocentesis kits, cables and minimally invasive tissue and thrombus removal devices, electrophysiology recording and mapping systems, including refurbishment, and software inclusive of accessory devices. Distribution of penile prosthesis, implants for continence, accessories, and surgical tools, fiber optic laser delivery devices. Distribution of medical laser systems. The installation of peripheral intervention systems (including minimally invasive tissue and thrombus removal devices) and ultrasound imaging systems and service (software upgrades and updates) of capital equipment.

Original Registration Date: 2017-05-08
Latest Revision Date: 2023-08-29

Effective Date: 2023-09-02
Expiry Date: 2026-09-01

Certificate No: **MD 670368**

Location	Registered Activities
Boston Scientific Corporation 100 Boston Scientific Way Marlborough Massachusetts 01752 USA	Design and development of devices in the areas of Gastroenterology, Nephrology, Gynecology, Urology, Endoscopy, Biliary and General Surgery (including Minimally Invasive Surgical Procedures). These products include: biliary stents, ureteral stents, pancreatic stents, drainage catheters, introducer catheters, urological catheters, percutaneous catheters and guide catheters, biliary devices, retrieval devices, feeding devices, cannulas, endoscopes, irrigation/drainage devices and sets, fluid administration and infusion devices, inflators, ligators, dilators, connecting tubes, adaptors, access sheaths, percutaneous access needles, aspiration needles, injection needles, endotherapy electrode systems, fiber optic laser delivery devices, sutures and suturing devices, nephrostomy devices, guidewires, biopsy devices, surgical mesh, polypectomy devices, hemostasis devices, torque devices, endoscopic valves, endoscope channel support kits, biopsy caps, locking devices, bladder evacuators and sphincterotomes, penile prosthesis implants for continence, accessories and surgical tools, medical laser systems and accessories.

Original Registration Date: 2017-05-08
Effective Date: 2023-09-02
Latest Revision Date: 2023-08-29
Expiry Date: 2026-09-01

Certificate No: **MD 670368**

Location	Registered Activities
Boston Scientific Corporation 4100 Hamline Ave. N. St. Paul Minnesota 55112 USA	Design and development of medical devices in the areas of Electrosurgical Applications (including Electrophysiology, Urology), cardiovascular and minimally invasive surgical and interventional procedures. These products include: cardiac ablation catheters, diagnostic mapping, pacing and recording catheters, generator equipment, cables, fluid filling devices, electrosurgical instruments and generators pericardiocentesis kits, tubing sets, fluid circulation pumps, and diagnostic software and recording systems inclusive of accessory devices. Design, manufacture, distribution, service and refurbishment of electrophysiology recording and mapping systems and software inclusive of accessory devices. Manufacture of electrosurgical instruments and generators. Manufacture, distribution and service of cardiac ablation systems inclusive of accessory devices. Distribution of urological devices such as generators and software for generators. Manufacture and service of medical laser systems and accessories. Manufacture and sterilization of penile prosthesis and associated accessories and surgical tools, implants for incontinence and associated accessories and surgical tools. Manufacture, installation, service and distribution of atherectomy angioplasty devices systems and accessories and minimally invasive tissue and thrombus removal devices. Manufacture, distribution, service and installation of ultrasound imaging systems inclusive of accessory devices. Manufacture and service of medical device electronic systems associated with diagnostics, monitoring, and therapy. Manufacture, service and distribution of Endoscope systems and accessories.
Boston Scientific Technology & Engineering Services Pvt. Ltd. 3rd Floor, Bestech Business Tower Sector 48 Sohna Road Gurgaon Haryana 122 018 India	The design and development of devices in the areas of Cardiovascular (including Cardiovascular Interventions), Peripheral (including Peripheral Interventions), Gynecology, Urology and Endoscopy, Neurology (including Neurovascular) and electrosurgical applications (including Electrophysiology) Radiology, Biliary. These products include Introducer sheath and kits, Vascular access catheter, microcatheters, Guide wires, Hemostasis devices, Thrombus catheter devices, Percutaneous access needles, Biopsy Cap and Locking Devices, Micro and Angled Support Catheters, Electrosurgical instruments & generators and device software. Design and development of external instrumentation for implantable cardiac monitors, implantable cardiac pulse generators and implantable cardioverter defibrillators including implantable cardiac pacing and defibrillation leads.

Original Registration Date: 2017-05-08
Effective Date: 2023-09-02
Latest Revision Date: 2023-08-29
Expiry Date: 2026-09-01

Certificate No: **MD 670368**

Location	Registered Activities
Boston Scientific Medical Device (Malaysia) SDN BHD PMT 741, Persiaran Cassia Selatan 1, Taman Perindustrian Batu Kawan, 14110 Bandar Cassia, Pulau Pinang Malaysia	Manufacture and distribution of Sterile Biopsy forceps, balloon catheters and fiber optic laser delivery devices.
BSC Medical Device Technology (Shanghai) Co., Ltd. Unit 3005, Hong Kong Prosperity Tower No. 763 Mengzi Road Huangpu District Shanghai China	Design and development of medical devices in the areas of Cardiovascular (including Cardiovascular Interventions), Electrosurgical Applications (including Electrophysiology), Urology, Endoscopy and Cardiac Rhythm Management. These products include Diagnostic software and recording system, Diagnostic mapping, thrombus removal devices, Laser system, endotherapy electrode system, tachy device, multi sensor for heart failure, brady device, insertable cardiac monitor, next generation programmer, MICS (Medical Implant Communication Service) dongle, 3G USB dongle, Electrocardiograph, leadless pacer communication interface pacing system analyzer, Lead-less pacer, monitor with consulting, monitor, cardiac monitor and Cardiac Resynchronization Therapy device.
Boston Scientific Corporation 10700 Bren Road West Minnetonka Minnesota 55343 USA	Manufacture of components for penile prostheses, components for implants for incontinence, and associated accessories.
Boston Scientific Limited Cashel Road Clonmel Co.Tipperary Ireland	Design development and manufacture of penile prosthesis. Service of medical device electronic systems associated with diagnostics, monitoring and therapy.
Boston Scientific Corporation 11810 Wills Road Alpharetta Georgia 30009 USA	Manufacture and distribution of endoscope accessories and endoscopic procedure kits.

Original Registration Date: 2017-05-08

Effective Date: 2023-09-02

Latest Revision Date: 2023-08-29

Expiry Date: 2026-09-01

Certificate No: **MD 670368**

Location	Registered Activities
Boston Scientific Technology & Engineering Services Pvt. Ltd. Cummins India Office Campus 5th Floor, Tower-B, Survey No. 21, Baner Balewadi Road Balewadi Pune Maharashtra 411045 India	The design and development of devices in the areas of Cardiovascular (including Cardiovascular Interventions), Peripheral (including Peripheral Interventions), Gynecology, Urology and Endoscopy, Neurology (including Neurovascular) and electrosurgical applications (including Electrophysiology) Radiology, Biliary. These products include Introducer sheath and kits, Vascular access catheter, microcatheters, Guide wires, Hemostasis devices, Thrombus catheter devices, Percutaneous access needles, Biopsy Cap and Locking Devices, Micro and Angled Support Catheters.
Guidant Puerto Rico B.V. a wholly owned subsidiary of Boston Scientific Corporation No. 12, Road 698 Dorado 00646-3311 Puerto Rico	Manufacture of guide catheters. Manufacture of medical device components and subassemblies for gastroenterology, endoscopy and biliary medical devices. Manufacture of minimally invasive tissue and thrombus removal devices.
Boston Scientific International Sdn. Bhd PMT 741 Persiaran Cassia Selatan 1 Taman Perindustrian Batu Kawan Bandar Cassia Pulau Pinang 14110 Malaysia	The distribution of devices in the areas of cardiovascular (including Cardiovascular Interventions), implantable cardiac pulse generators and implantable cardioverter defibrillators including implantable cardiac pacing and defibrillation leads, Peripheral (including Peripheral Interventions), Electrosurgical Applications (including Electrophysiology), Gastroenterology, Nephrology, Neurology (including Neurovascular), Gynecology, Urology, Radiology, Endoscopy, Biliary, General Surgery (including Minimally Invasive Surgical Procedures), and Embolic Protection.
Boston Scientific Corporation 309 Waverley Oaks Rd Waltham Massachusetts 02452 USA	Design of pacing and recording catheters and recording and mapping systems and accessories.

Original Registration Date: 2017-05-08

Effective Date: 2023-09-02

Latest Revision Date: 2023-08-29

Expiry Date: 2026-09-01

bsi.

By Royal Charter

Registravimo sertifikatas

KOKYBĖS VALDYMO SISTEMA - ISO 13485:2016 IR EN ISO 13485:2016

Šiuo patvirtinama, kad:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Massachusetts
01752
JAV

Turi sertifikatą, kurio numeris: **MD 670368**

ir taiko kokybės vadybos sistemą, atitinkančią ISO 13485:2016 ir EN ISO 13485:2016 reikalavimus šiai taikymo sričiai:

Žr. apimties lapą.

BSI vardu:

[redacted]

Pradinė registracijos data: 2017-05-08

Naujausios revizijos data: 2023-08-29

Galiojimo pabaigos data: 2026-09-01

[redacted]

UKAS MANAGEMENT SYSTEMS 0003

...making excellence a habit.™

Sertifikatas nr.: **MD 670368**

Registruota apimtis:

Širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), periferinių (įskaitant periferines intervencijas), elektrochirurgijos (įskaitant elektrofiziologiją), gastroenterologijos, nefrologijos, neurologijos (įskaitant neurovaskulinę), ginekologijos, urologijos, radiologijos, endoskopijos, tulžies, bendrosios chirurgijos (įskaitant minimaliai invazines chirurgines procedūras) ir apsaugos nuo embolijos prietaisų projektavimas, kūrimas, gamyba ir platinimas. Gamybos veikla, susijusi su radijo bangų ir krioabliacijos prietaisais bei priedais. Gaminiai: Tulžies stentai, širdies ir kraujagyslių stentai, šlapimtakių stentai, kasos stentai; balioniniai kateteriai, angiografiniai kateteriai, mikrokateteriai, drenažo kateteriai, Introdiuseriai, urologiniai kateteriai, perkutaniniai kateteriai, abliacijos kateteriai ir kreipiamieji kateteriai; tulžies įtaisai, chirurginis tinklelis, elektrochirurginiai instrumentai ir generatoriai, generatorių programinė įranga, paėmimo prietaisai, padavimo prietaisai, kaniulės, elektrodai, endoskopai, tyrimo pirštinės, drėkinimo / drenavimo prietaisai ir rinkiniai, skysčių cirkuliacijos siurbliai, skysčių administravimo, užpildymo ir infuzijos prietaisai, pripūtimo įrenginiai, ligatoriai, dilatatoriai, jungiamieji vamzdeliai, prieigos apvalkalai, vamzdelių rinkiniai; adapteriai; kairiojo prieširdžio priedo (LAA) uždarymo įtaisai ir priedai; perkutaninės prieigos adatos, aspiracinės adatos, injekcinės adatos, įvedimo adatos, endoterapijos elektrodų sistema, šviesolaidinio lazerio tiekimo prietaisai; radijo bangų ir krioabliacijos sistema, sistemos ir priedai; siūlai ir siuvimo prietaisai, švirkštai, kraujagyslių įvedimo įtaisai, nefrostomijos prietaisai, vieliniai kreiptuvai, biopsijos prietaisai, polipektomijos prietaisai, hemostazės prietaisai, sukimo momento prietaisai, rankogalių rinkiniai, endoskopiniai vožtuvai, endoskopo kanalų palaikymo rinkiniai, biopsijos dangteliai, fiksavimo įtaisai, šlapimo pūslės evakuatoriai, sfinkterotomos, apsaugos sistemos ir embolizacijos ritės, ultragarso vaizdo kateteriai, paėmimo apvalkalai, diagnostikos programinė įranga ir įrašymo sistemos, diagnostikos kartografavimo, stimuliavimo ir įrašymo kateteriai, įskaitant priedus, perikardiocentezės rinkiniai; kabeliai. Minimaliai invaziniai audinių ir trombų šalinimo prietaisai, aterektomijos angioplastikos prietaisai, elektrofiziologinės registravimo ir kartografavimo sistemos, įskaitant atnaujinimą, ir programinė įranga, įskaitant priedus. Ultragarsinio tyrimo sistemos.
Išoriniai implantuojamų širdies monitorių, implantuojamų širdies impulsų generatorių ir implantuojamų kardioverterių defibriliatorių prietaisai, įskaitant implantuojamus širdies stimuliavimo ir defibriliacijos laidus. Varpos protezų ir susijusių priedų, šlapimo nelaikymo implantų ir susijusių priedų bei chirurginių įrankių projektavimas, kūrimas, gamyba ir sterilizavimas. Medicininių lazerinių sistemų ir priedų gamyba. Medicinos prietaisų elektroninių sistemų, susijusių su diagnostika, stebėjimu ir terapija, gamyba ir aptarnavimas.
Periferinių intervencinių sistemų (įskaitant minimaliai invazinius audinių ir trombų šalinimo prietaisus) ir ultragarso tyrimo sistemų įrengimas ir kapitalinės įrangos aptarnavimas (programinės įrangos atnaujinimas ir versijos keitimas).
Medicinos prietaisų komponentų ir mazgų, skirtų virškinimo trakto, endoskopijos ir tulžies medicinos prietaisams, gamyba.

Pradinė registracijos data: 2017-05-08 Įsigaliojimo data: 2023-09-02
Naujausios revizijos data: 2023-08-29 Galiojimo pabaigos data: 2026-09-01

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
Boston Scientific Corporation 302 Parkway Global Park Heredia Kosta Rika	Širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), periferinių (įskaitant periferines intervencijas), elektrochirurgijos (įskaitant elektrofiziologiją), gastroenterologijos, nefrologijos, neurologijos (įskaitant neurovaskulines) ginekologijos, urologijos, endoskopijos, tulžies ir bendrosios chirurgijos (įskaitant minimaliai invazines chirurgines procedūras) prietaisų projektavimas, kūrimas, gamyba. Šie gaminiai apima vielinius kreiptuvus, diagnostinius žemėlapius, stimuliavimo ir įrašymo kateterius, įskaitant priedus, ir apsaugos nuo embolijos sistemas. Širdies diagnostikos, kartografavimo ir abliacijos kateterių, vielinių kreiptuvų, sukimo momento prietaisų, skirtų naudoti su aterektomija, ir minimaliai invazinių audinių bei trombų šalinimo prietaisų gamyba; perikardiocentezės rinkiniai. Infliatorių, hemostazės prietaisų, sukimo momento prietaisų, įvedimo adatų ir embolizacijos spiralių projektavimas ir tobulinimas. Balioninių kateterių, angiografinių kateterių, mikrokateterių, šlapimtakių stentų, drenažo kateterių, urologinių kateterių, jungiamųjų vamzdelių ir įvedimo adatų projektavimas ir tobulinimas.
Boston Scientific Corporation 2546 First Street, Propark El Coyol, Alajuela Kosta Rika	Prietaisų gamyba periferinės (įskaitant periferines intervencijas), širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurgijos (įskaitant elektrofiziologiją), gastroenterologijos, nefrologijos, ginekologijos, urologijos, endoskopijos, tulžies, bendrosios chirurgijos ir minimaliai invazinės chirurgijos (įskaitant minimaliai invazinę chirurgiją) srityse ir apsaugą nuo embolijos. Gamybos veikla, susijusi su radijo bangų ir abliacijos prietaisais bei priedais. Produktai: tulžies stentai, šlapimtakių stentai, drenažo kateteriai, įvedimo kateteriai, urologiniai kateteriai, perkutaniniai kateteriai, tulžies įtaisai, ligatoriai, adapteriai, perkutaninės prieigos adatos, injekcinės adatos, siūlai ir siuvimo prietaisai, nefrostomijos prietaisai, vieliniai kreiptuvai, biopsijos prietaisai, polipai šalinimo prietaisai, hemostazės prietaisai, sukimo momento įtaisai, sfinkterotomos, apsaugos nuo embolijos sistemos, skysčių užpildymo prietaisai, ultragarso vaizdo kateteriai, elektrodai, kaniulės, paėmimo įtaisai, paėmimo apvalkalai ir endoskopai. Intravaskulinių rekanalizavimo sistemų gamyba.
Boston Scientific Corporation 300 Boston Scientific Way Marlborough Massachusetts 01752 JAV	Administracinė veikla.

Pradinė registracijos data: 2017-05-08
Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02
Galiojimo pabaigos data: 2026-09-01

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
Boston Scientific Corporation 780 Brookside Drive Spencer Indiana 47460 JAV	Prietaisų gamyba periferinės (įskaitant periferines intervencijas), elektrochirurgijos (įskaitant elektrofiziologiją), gastroenterologijos, nefrologijos, ginekologijos, urologijos, endoskopijos, tulžies, bendrosios chirurgijos ir minimaliai invazinės chirurgijos (įskaitant minimaliai invazinę chirurgiją) srityse ir apsaugą nuo embolijos. Gaminiai: Chirurginiai tinkleliai, tulžies stentai, šlapimtakių stentai, kasos stentai; drenažo kateteriai, įvedimo kateteriai, urologiniai kateteriai, perkutaniniai kateteriai ir nukreipiamieji kateteriai; tulžies įtaisai, paėmimo prietaisai, maitinimo įtaisai, kaniulės, endoskopai, tyrimo pirštinės, drėkinimo ir (arba) drenažo prietaisai ir rinkiniai, skysčių įvedimo ir infuzijos prietaisai, pripūtimo įtaisai, ligatoriai, dilatatoriai, jungiamieji vamzdeliai, prieigos apvalkalų adapteriai; perkutaninės prieigos adatos, aspiracinės adatos, injekcinės adatos, įvedimo adatos, endoterapijos elektrodų sistema; švirkštai, kraujagyslių įvedimo įtaisai, nefrostomijos prietaisai, kreipiamieji laidai, biopsijos prietaisai, polipektomijos prietaisai, hemostazės prietaisai, sukimo momento prietaisai, rankogalių rinkiniai, biopsijos dangteliai, fiksavimo įtaisai, šlapimo pūslės evakuatoriai ir sfinkterotomos. Medicinos prietaisų priedų, skirtų naudoti su implantuojamaisiais kardioverterio defibriliatoriais, įskaitant implantuojamus širdies defibriliacijos laidus, gamyba.

Pradinė registracijos data: 2017-05-08
Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02
Galiojimo pabaigos data: 2026-09-01

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
Boston Scientific Ltd. 2 Paget Rd Unit #2 Brampton Ontario L6T 5G3 Kanada	Prietaisų gamyba (ženklinimas) ir platinimas širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), periferinius (įskaitant periferines intervencijas), elektrochirurgijos (įskaitant elektrofiziologiją), gastroenterologijos, nefrologijos, neurologijos (įskaitant neurovaskulines), ginekologijos, urologijos, radiologijos, Endoskopija, tulžies takų, bendroji chirurgija (įskaitant minimaliai invazines chirurgines procedūras) ir apsaugos nuo embolijos srityse. Gaminiai: Tulžies stentai, širdies ir kraujagyslių stentai, šlapimtakio stentai, kasos stentai, angiografiniai kateteriai, drenažo kateteriai, įvedimo kateteriai, urologiniai kateteriai, perkutaniniai kateteriai, abliacijos kateteriai ir kreipiamieji kateteriai, tulžies kanalai, elektrochirurginiai instrumentai ir generatoriai, generatorių programinė įranga, paėmimo prietaisai, maitinimo įtaisai, kaniulės, apžiūros pirštinės, drėkinimo/drenažo prietaisai ir rinkiniai, skysčių cirkuliaciniai siurbliai, skysčių administravimo, užpildymo ir infuzijos prietaisai, pripūtimo įtaisai, ligatoriai, dilatatoriai, jungiamieji vamzdeliai, prieigos apvalkalai, vamzdelių rinkiniai, adapteriai, kairiojo prieširdžio priedo (LAA) uždarymo įtaisai ir pagalbiniai prietaisai, perkutaninės prieigos adatos, aspiracinės adatos, injekcinės adatos, įvedimo adatos, endoterapijos elektrodų sistema, radijo bangų abliacijos sistema, sistemos ir priedai, chirurginiai tinkleliai, siūlai ir siuvimo įtaisai, švirkštai, kraujagyslių įvedikliai, nefrostomijos prietaisai, kreipikliai, biopsijos prietaisai , polipektomijos prietaisai, hemostazės prietaisai, sukimo momento prietaisai, endoskopiniai vožtuvai, endoskopo kanalų palaikymo rinkiniai, manžečių rinkiniai, biopsijos dangteliai, fiksavimo įtaisai, šlapimo pūslės evakuatoriai, sfinkterotomos, apsaugos nuo embolijos sistemos, ultragarso vaizdo kateteriai, paėmimo apvalkalai, diagnostikos programinė įranga ir įrašymo sistemos, diagnostikos kartografavimo, stimuliavimo ir registravimo kateteriai, įskaitant priedus, perikardiocentezės rinkinius, kabelius ir minimaliai invazinius audinių bei trombų šalinimo prietaisus, elektrofiziologines registravimo ir kartografavimo sistemas, įskaitant atnaujinimą, ir programinę įrangą, įskaitant priedus. Varpos protezų, sulaikymui skirtų implantų, priedų ir chirurginių įrankių, šviesolaidinių lazerinių įvedimo prietaisų platinimas. Medicininių lazerinių sistemų ir priedų platinimas. Periferinių intervencinių sistemų (įskaitant minimaliai invazinius audinių ir trombų šalinimo prietaisus) ir ultragarso tyrimo sistemų įrengimas ir kapitalinės įrangos aptarnavimas (programinės įrangos atnaujinimas ir versijos keitimas).

Pradinė registracijos data: 2017-05-08
Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02
Galiojimo pabaigos data: 2026-09-01

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
Boston Scientific Corporation 100 Boston Scientific Way Marlborough Massachusetts 01752 JAV	Prietaisų projektavimas ir tobulinimas gastroenterologijos, nefrologijos, ginekologijos, urologijos, endoskopijos, tulžies ir bendrosios chirurgijos srityse (įskaitant minimaliai invazines chirurgines procedūras). Šie produktai yra: tulžies stentai, šlapimtakių stentai, kasos stentai, drenažo kateteriai, įvedimo kateteriai, urologiniai kateteriai, perkutaniniai kateteriai ir kreipiamieji kateteriai, tulžies įtaisai, paėmimo prietaisai, maitinimo prietaisai, kaniulės, endoskopai, drėkinimo / drenažo prietaisai ir rinkiniai, skysčių įvedimo ir infuzijos prietaisai, infliatoriai, ligatoriai, plėtikliai, jungiamieji vamzdeliai, adapteriai, prieigos apvalkalai, perkutaninės prieigos adatos, aspiracinės adatos, injekcinės adatos, endoterapijos elektrodų sistemos, optinio pluošto lazerio tiekimo prietaisai, siūlai ir siuvimo prietaisai, nefrostomijos prietaisai, kreipiamieji laidai, biopsijos prietaisai , chirurginis tinklelis, polipektomijos prietaisai, hemostazės prietaisai, sukimo momento prietaisai, endoskopiniai vožtuvai, endoskopo kanalų atramos rinkiniai, biopsijos dangteliai, fiksavimo įtaisai, šlapimo pūslės evakuatoriai ir sfinkterotomos, varpos protezų implantai, skirti sulaikymui, priedai ir chirurginiai įrankiai, medicininės lazerinės sistemos ir priedai.

Pradinė registracijos data: 2017-05-08
Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02
Galiojimo pabaigos data: 2026-09-01

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
Boston Scientific Corporation 4100 Hamline Ave. N. St. Paul Minnesota 55112 JAV	Medicinos prietaisų projektavimas ir tobulinimas elektrochirurginių pritaikymų (įskaitant elektrofiziologiją, urologiją), širdies ir kraujagyslių bei minimaliai invazinių chirurginių ir intervencinių procedūrų srityse. Šie produktai yra: širdies abliacijos kateteriai, diagnostikos kartografavimo, stimuliavimo ir įrašymo kateteriai, generatoriaus įranga, kabeliai, skysčių pildymo įtaisai, elektrochirurginiai instrumentai ir generatoriai perikardocentezės rinkiniai, vamzdelių rinkiniai, skysčių cirkuliacijos siurbliai ir diagnostikos programinė įranga bei įrašymo sistemos, įskaitant priedus. Elektrofiziologijos registravimo ir kartografavimo sistemų ir programinės įrangos, įskaitant priedus, projektavimas, gamyba, platinimas, aptarnavimas ir atnaujinimas. Elektrochirurginių instrumentų ir generatorių gamyba. Širdies abliacijos sistemų, įskaitant priedus, gamyba, platinimas ir aptarnavimas. Urologinių prietaisų, tokių kaip generatoriai ir programinė įranga, platinimas . Medicininių lazerinių sistemų ir priedų gamyba ir aptarnavimas. Varpos protezų ir susijusių priedų bei chirurginių įrankių, šlapimo nelaikymo implantų ir susijusių priedų bei chirurginių įrankių gamyba ir sterilizavimas. Aterektomijos angioplastikos prietaisų sistemų ir priedų bei minimaliai invazinių audinių ir trombų šalinimo prietaisų gamyba, montavimas, aptarnavimas ir platinimas. Ultragarso tyrimo sistemų, įskaitant priedus, gamyba, platinimas, aptarnavimas ir montavimas. Medicinos prietaisų elektroninių sistemų, susijusių su diagnostika, stebėjimu ir terapija, gamyba ir aptarnavimas. Endoskopų sistemų ir priedų gamyba, aptarnavimas ir platinimas.
Boston Scientific Technology & Engineering Services Pvt. Ltd. 3rd Floor, Bestech Business Tower Sector 48 Sohna Road Gurgaon Haryana 122 018 Indija	Širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), periferinių (įskaitant periferines intervencijas), ginekologijos, urologijos ir endoskopijos, neurologijos (įskaitant neurovaskulines) ir elektrochirurgijos (įskaitant elektrofiziologiją), radiologijos, tulžies ligų prietaisų projektavimas ir tobulinimas. Šie gaminiai apima įvedimo apvalkalą ir rinkinius, kraujagyslių prieigos kateterius, mikrokateterius, vielinius kreiptuvus, hemostazės prietaisus, trombų kateterio prietaisus, perkutaninės prieigos adatas, biopsijos dangtelį ir fiksavimo įtaisus, mikro ir kampinius atraminius kateterius, elektrochirurginius instrumentus ir generatorius bei įrenginių programinę įrangą. Implantuojamųjų širdies monitorių, implantuojamų širdies impulsų generatorių ir implantuojamųjų kardioverterių defibriliatorių, įskaitant implantuojamus širdies stimuliavimo ir defibriliacijos laidus, projektavimas ir tobulinimas.

Pradinė registracijos data: 2017-05-08
Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02
Galiojimo pabaigos data: 2026-09-01

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
Boston Scientific Medical Device (Malaizija) SDN BHD PMT 741, Persiaran Cassia Selatan 1, Taman Perindustrian Batu Kawan, 14110 Bandar Cassia, Pulau Pinang Malaizija	Sterilių biopsijos žnyplių, balioninių kateterių ir šviesolaidinių lazerinių tiekimo prietaisų gamyba ir platinimas.
BSC Medical Device Technology (Shanghai) Co., Ltd. Unit 3005, Hong Kong Prosperity Tower No. 763 Mengzi Road Huangpu District Shanghai Kinija	Medicinos prietaisų kūrimas ir kūrimas širdies ir kraujagyslių sistemos (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurgijos (įskaitant elektrofiziologiją), urologijos, endoskopijos ir širdies ritmo valdymo srityse. Šie gaminiai apima diagnostikos programinę įrangą ir įrašymo sistemą, diagnostinį kartografavimą, trombų šalinimo prietaisus, lazerių sistemas, endoterapijos elektrodų sistemas, tachikardijos prietaisus, širdies nepakankamumo multisensorius, Brady prietaisus, įkišamus širdies monitorius, naujos kartos programatorius, MICS (Medical Implant Communication Service) raktus, 3G USB raktus, elektrokardiografus, bešvinius širdies stimuliatoriaus ryšio sąsajos stimuliavimo sistemos analizatorius, stimuliatorius, monitorius su konsultacija, monitoriumi, širdies monitoriumi ir širdies
Boston Scientific Corporation 10700 Bren Road West Minnetonka Minnesota 55343 JAV	Varpos protezų komponentų, šlapimo nelaikymo implantų komponentų ir susijusių priedų gamyba.
Boston Scientific Limited Cashel Road Clonmel Co.Tipperary Ireland	Varpos protezo konstrukcijos kūrimas ir gamyba. Medicinos prietaisų elektroninių sistemų, susijusių su diagnostika, stebėjimu ir terapija aptarnavimas.
Boston Scientific Corporation 11810 Wills Road Alpharetta Georgia 30009 JAV	Endoskopų priedų ir endoskopinių procedūrų rinkinių gamyba ir platinimas.

Pradinė registracijos data: 2017-05-08 Įsigaliojimo data: 2023-09-02

Naujausios revizijos data: 2023-08-29 Galiojimo pabaigos data: 2026-09-01

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
Boston Scientific Technology & Engineering Services Pvt. Ltd. Cummins India Office Campus 5th Floor, Tower-B, Survey No. 21, Baner Balewadi Road Balewadi Pune Maharashtra 411045 Indija	Širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), periferinių (įskaitant periferines intervencijas), ginekologijos, urologijos ir endoskopijos, neurologijos (įskaitant neurovaskulines) ir elektrochirurgijos (įskaitant elektrofiziologiją), radiologijos, tulžies ligų prietaisų projektavimas ir tobulinimas. Šie gaminiai apima įvedimo apvalkalą ir rinkinius, kraujagyslių prieigos kateterius, mikrokateterius, vielinius kreiptuvus, hemostazės prietaisus, trombų kateterio prietaisus, perkutaninės prieigos adatas, biopsijos dangtelį ir fiksavimo įtaisus, mikro ir kampinius atraminius kateterius.
Guidant Puerto Rico B.V. visiškai boston Scientific Corporation priklausanti dukterinė įmonė No. 12, Road 698 Dorado 00646-3311 Puerto Rico	Kreipiamųjų kateterių gamyba. Medicinos prietaisų komponentų ir mazgų, skirtų virškinimo trakto, endoskopijos ir tulžies medicinos prietaisams, gamyba. Minimaliai invazinių audinių ir trombų šalinimo prietaisų gamyba.
Boston Scientific International Sdn. Bhd PMT 741 Persiaran Cassia Selatan 1 Taman Perindustrian Batu Kawan Bandar Cassia Pulau Pinang 14110 Malaizija	Širdies ir kraujagyslių sistemos (įskaitant širdies ir kraujagyslių intervencijas), implantuojamų širdies impulsų generatorių ir implantuojamų kardioverterių defibriliatorių, įskaitant implantuojamus širdies stimuliavimo ir defibriliacijos laidus, periferinių (įskaitant periferines intervencijas), elektrochirurgijos taikymo (įskaitant elektrofiziologiją), gastroenterologijos, neurologijos, neurologijos (įskaitant neurovaskulines), ginekologijos, urologijos, endoskopijos, tulžies ir bendrosios chirurgijos (įskaitant minimaliai invazines chirurgines procedūras) srities prietaisų platinimas.
Boston Scientific Corporation 309 Waverley Oaks Rd Waltham Massachusetts 02452 JAV	Stimuliacijos ir registravimo kateterių ir registravimo bei kartografavimo sistemų ir priedų projektavimas.

Pradinė registracijos data: 2017-05-08
Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02
Galiojimo pabaigos data: 2026-09-01

EC CERTIFICATE

Number: **3812454CE01**

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough, MA 01752
United States of America

For the product category(ies)

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 1 July 2014

DEKRA hereby declares that the above-mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above-mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

DEKRA Certification B.V.

[redacted]

[redacted]

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

EC CERTIFICATE

Number: **3812454CE01**

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough, MA 01752
United States of America

For the product category(ies)

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August 2012 concerning medical devices manufactured utilising tissue of animal origin. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: **26 May 2024**
Issued for the first time: 1 July 2014
Revised: 21 December 2018
Reissued: 30 April 2020

[redacted]

[redacted]

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: **3812454CE01**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Issued to:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States of America

This certificate covers the following location(s):

Location Code	Company name / address	Location Code	Company name / address
MAR2	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA	CR2	Boston Scientific Corporation 2546 First Street, Propark El Coyol Alajuela Costa Rica
COR	Boston Scientific Limited Business & Technology Park Model Farm Rd Cork, Ireland	GAL	Boston Scientific Limited Ballybrit Business Park Galway, Ireland
COV	Boston Scientific Corporation 8 Industrial Drive Coventry, RI 02816 USA	KER	Boston Scientific International BV European Centre of Operations Vestastraat 6, 6468 EX Kerkrade, The Netherlands

DEKRA Certification B.V.

[redacted]

[redacted]

ADDENDUM

Belonging to certificate: **3812454CE01**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Issued to:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States of America

This certificate covers the following location(s): continued

Location Code	Company name / address		Location Code	Company name / address
CR1	Boston Scientific Corporation 302 Parkway Global Park, Heredia Costa Rica		MAR	Boston Scientific Corporation 100 Boston Scientific Way Marlborough, MA 01752 USA
MG2	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA		SJ2	Boston Scientific Corporation 150 Baytech Drive San Jose, CA 95134 USA
SP	Boston Scientific Corporation 4100 Hamline Avenue N. St. Paul, MN 55112 USA		SPE	Boston Scientific Corporation 780 Brookside Drive Spencer, IN 47460 USA

DEKRA Certification B.V.

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DEKRA Certification B.V. is Notified Body with ID no 0344

ADDENDUM

Belonging to certificate: **3812454CE01**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Issued to:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States of America

This certificate covers the following location(s): continued

Location Code	Company name / address		Location Code	Company name / address
QUI	Boston Scientific Corporation Marina Bay Customer Fulfillment Center 500 Commander Shea Blvd Quincy, MA 02171 USA		ECU	Symetis SA Chemin de la Venoge 11 1024 Ecublens Switzerland
CHP	ACURATE Indústria e Comércio LTDA Chapecó Site Rua Apiuna, 520-D Cristo Rei Chapecó / SC – Brazil		BHM	ACURATE Indústria e Comércio LTDA BHM Site (Belo Horizonte Site) Avenida General David Sarnoff, 344 Lote 02 – Quadra 31A Cidade Industrial Contagem/MG – Brazil
PEN	Boston Scientific Medical Device (Malaysia) Sdn. Bhd. PMT 741, Persiaran Cassia Selatan 1 Taman Perindustrian Batu Kawan 14110 Bandar Cassia, Pulau Pinang, Malaysia			

[redacted]

DEKRA Certification B.V. is Notified Body with ID no 0344

ADDENDUM

Belonging to certificate: **3812454CE01**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Issued to:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States of America

Initial date: 1 July 2014
Revision date: 1 June 2020

[redacted]

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

„DEKRA“

EB SERTIFIKATAS

Numeris: **3812454CE01** **1/2**

Visiško kokybės užtikrinimo sistema

Direktyva 93/42/EEB dėl medicinos prietaisų, II priedas, išskyrus (4)
(IIa, IIb arba III klasės prietaisai ir sterilūs I klasės prietaisai bei sistemos ar procedūrų rinkiniai)

Gamintojas:

“Boston Scientific Corporation”

300 Boston Scientific Way
Marlborough, MA 01752
Jungtinės Amerikos Valstijos

Gaminio kategorijai(-oms)

Medicinos prietaisai ir priedai, skirti minimaliai invazinėms tulžies, širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurginėms, endoskopinės chirurgijos, endoskopinėms, gastroenterologinėms, ginekologinėms, nefrologinėms, neurologinėms (įskaitant neurovaskulines), periferinėms (įskaitant periferines intervencijas) ir urologinėms procedūroms.

DEKRA suteikia teisę naudoti žemiau nurodytą EB paskelbtosios įstaigos identifikavimo numerį greta CE atitikties ženklo gaminiams, kurie atitinka numatytą techninę dokumentaciją ir jiems taikomos EB direktyvos nuostatas.

0344

Dokumentai, kurie sudaro šio sertifikato pagrindą:

Pažyma apie sertifikavimą 3812454CN, pirmą kartą registruota 2014 m. liepos 1d.
Priedas, pirmą kartą registruotas 2014 m liepos 1 d.

Šiuo dokumentu „DEKRA“ pareiškia, jog anksčiau minėtas gamintojas atitinka susijusias 'Besluit Medische Hulpmiddelen' nuostatas, Nyderlandų perkeltą 1993 birželio 14 d. Tarybos direktyvą 93/42/EEB dėl medicinos prietaisų, įskaitant visus vėlesnius pakeitimus. Gamintojas aukščiau minėtai gaminių kategorijai įdiegė kokybės užtikrinimo sistemą projektavimo, gamybos ir baigiamojo patikrinimo etapuose, kuri apima gamybos aspektus, susijusius su sterilių sąlygų užtikrinimu ir palaikymu pagal 1993 birželio 14 d. Tarybos direktyvos 93/42/EEB II priedo nuostatas, ir yra periodiškai tikrinama.

“DEKRA Certification B.V.”

/parašas/

B.T.M. Holtus
Vykdomasis direktorius

/parašas/

J.A. van Vugt
Sertifikavimo vadybininkas

“DEKRA Certification B.V.” yra paskelbtoji įstaiga, kurios ID Nr. 0344

„DEKRA Certification B.V.” Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, Nyderlandai
Tel. +31 88 96 83000 Faks. +31 88 96 83100 www.dekra-product-safety.com Įmonės registracijos numeris 09085396

„DEKRA“

EB SERTIFIKATAS

Numeris: **3812454CE01** **2/2**

Visiško kokybės užtikrinimo sistema

Direktyva 93/42/EEB dėl medicinos prietaisų, II priedas, išskyrus (4)
(IIa, IIb arba III klasės prietaisai ir sterilūs I klasės prietaisai bei sistemos ar procedūrų rinkiniai)

Gamintojas:

“Boston Scientific Corporation”

300 Boston Scientific Way
Marlborough, MA 01752
Jungtinės Amerikos Valstijos

Gaminio kategorijai(-oms)

Medicinos prietaisai ir priedai, skirti minimaliai invazinėms tulžies, širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurginėms, endoskopinės chirurgijos, endoskopinėms, gastroenterologinėms, ginekologinėms, nefrologinėms, neurologinėms (įskaitant neurovaskulines), periferinėms (įskaitant periferines intervencijas) ir urologinėms procedūroms.

Be to, šiuo dokumentu „DEKRA“ pažymi, kad gamintojas atitinka 2012 rugpjūčio 8 d. Komisijos reglamento 722/2012 I priede keliamus reikalavimus dėl medicinos prietaisų, pagamintų naudojant gyvūninės kilmės audinius. Tiekiant į rinką III klasės prietaisus privalomas papildomas EB projekto tyrimo sertifikatas, parengtas pagal II (4) priedą.
Reikalinga informacija apie gamintojo kokybės valdymo sistemą, įskaitant infrastruktūrą ir nuorodas į atitinkamus dokumentus, susijusius produktus ir atliktus vertinimus yra pateikta pažymoje apie sertifikavimą, kuri yra neatsiejama šio sertifikato dalis.

Šis sertifikatas galioja iki:	**2024 gegužės 26 d.**
Pirmą kartą išduota:	2014 liepos 1 d.
Peržiūrėta:	2018 gruodžio 21 d.
Pakartotinai išduota:	2020 balandžio 30 d.

“DEKRA Certification B.V.”

/parašas/

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„DEKRA“

PRIEDAS

Priklausantis sertifikatui: **3812454CE01** **1/4**

CE ATITIKTIES ŽENKLINIMAS
MEDICINOS PRIETAISAI

Medicinos prietaisai ir priedai, skirti minimaliai invazinėms tulžies, širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurginėms, endoskopinės chirurgijos, endoskopinėms, gastroenterologinėms, ginekologinėms, nefrologinėms, neurologinėms (įskaitant neurovaskulines), periferinėms (įskaitant periferines intervencijas) ir urologinėms procedūroms.

Išduota:

“Boston Scientific Corporation”
300 Boston Scientific Way
Marlborough, MA 01752
Jungtinės Amerikos Valstijos

Šis sertifikatas apima šią(-ias) vietovę(-es):

Vietos kodas	Įmonės pavadinimas/adresas	Vietos kodas	Įmonės pavadinimas/adresas
MAR2	“Boston Scientific Corporation” 300 Boston Scientific Way Marlborough, MA 01752 JAV	CR2	“Boston Scientific Corporation” 2546 First Street, Propark El Coyol Alajuela Kosta Rika
COR	“Boston Scientific Limited” Business & Technology Park Model Farm Rd Cork, Airija	GAL	“Boston Scientific Limited” Ballybrit Business Park Galway, Airija
COV	“Boston Scientific Corporation” 8 Industrial Drive Coventry, RI 02816 JAV	KER	“Boston Scientific” International BV European Centre of Operations Vestastraat 6, 6468 EX Kerkrade, Nyderlandai

“DEKRA Certification B.V.”

/parašas/

B.T.M. Holtus
Vykdomasis direktorius

/parašas/

J.A. van Vugt
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„DEKRA“

PRIEDAS

Priklausantis sertifikatui: **3812454CE01** **2/4**

CE ATITIKTIES ŽENKLINIMAS
MEDICINOS PRIETAISAI

Medicinos prietaisai ir priedai, skirti minimaliai invazinėms tulžies, širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurginėms, endoskopinės chirurgijos, endoskopinėms, gastroenterologinėms, ginekologinėms, nefrologinėms, neurologinėms (įskaitant neurovaskulines), periferinėms (įskaitant periferines intervencijas) ir urologinėms procedūroms.

Išduota:

“Boston Scientific Corporation”
300 Boston Scientific Way
Marlborough, MA 01752
Jungtinės Amerikos Valstijos

Šis sertifikatas apima šią(-ias) vietovę(-es):

Vietos kodas	Įmonės pavadinimas/adresas	Vietos kodas	Įmonės pavadinimas/adresas
CR1	“Boston Scientific Corporation” 302 Parkway Global Park, Heredia Kosta Rika	MAR	“Boston Scientific Corporation” 100 Boston Scientific Way Marlborough, MA 01752 JAV
MG2	“Boston Scientific Corporation” Two Scimed Place Maple Grove, MN 55311 JAV	SJ2	“Boston Scientific Corporation” 150 Baytech Drive San Jose, CA 95134 JAV
SP	“Boston Scientific Corporation” 4100 Hamline Avenue N. St. Paul, MN 55112 JAV	SPE	“Boston Scientific Corporation”” 780 Brookside Drive Spencer, IN 47460 JAV

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/parašas/

B.T.M. Holtus
Vykdomasis direktorius

/parašas/

J.A. van Vugt
Sertifikavimo vadybininkas

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„DEKRA“

PRIEDAS

Priklausantis sertifikatui: **3812454CE01** **3/4**

CE ATITIKTIES ŽENKLINIMAS
MEDICINOS PRIETAISAI

Medicinos prietaisai ir priedai, skirti minimaliai invazinėms tulžies, širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurginėms, endoskopinės chirurgijos, endoskopinėms, gastroenterologinėms, ginekologinėms, nefrologinėms, neurologinėms (įskaitant neurovaskulines), periferinėms (įskaitant periferines intervencijas) ir urologinėms procedūroms.

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300 Boston Scientific Way
Marlborough, MA 01752
Jungtinės Amerikos Valstijos

Šis sertifikatas apima šią(-ias) vietovę(-es):

Vietos kodas	Įmonės pavadinimas/adresas		Vietos kodas	Įmonės pavadinimas/adresas
QUI	“Boston Scientific Corporation” Marina Bay Customer Fulfillment Center 500 Commander Shea Blvd Quincy, MA 02171		ECU	“Symetis SA“ Chemin de la Venoge 11 1024 Ecublens Šveicarija
CHP	“ACURATE Indústria e Comércio LTDA Chapecó Site Rua Apiuna, 520-D Cristo Rei Chapecó / SC -Brazilija		BHM	“ ACURATE Indústria e Comércio LTD“ BHM Site (Belo Horizonte Site) Avenida General David Sarnoff, 344 Lote 02 – Quadra 31A Cidade Industrial Contagem/MG - Brazilija
PEN	„Boston Scientific Medical Device (Malaysia) Sdn. Bhd.“ PMT 741, Persiaran Cassia Selatan 1 Taman Perindustrian Batu Kawan 14110 Bandar Cassia, Pulau Pinang, Malaizija			

DEKRA Certification B.V.”

/parašas/

B.T.M. Holtus
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/parašas/

J.A. van Vugt
Sertifikavimo vadybininkas

„DEKRA“

PRIEDAS

Priklausantis sertifikatui: **3812454CE01** **4/4**

CE ATITIKTIES ŽENKLINIMAS
MEDICINOS PRIETAISAI

Medicinos prietaisai ir priedai, skirti minimaliai invazinėms tulžies, širdies ir kraujagyslių (įskaitant širdies ir kraujagyslių intervencijas), elektrochirurginėms, endoskopinės chirurgijos, endoskopinėms, gastroenterologinėms, ginekologinėms, nefrologinėms, neurologinėms (įskaitant neurovaskulines), periferinėms (įskaitant periferines intervencijas) ir urologinėms procedūroms.

Išduota:

“Boston Scientific Corporation”
300 Boston Scientific Way
Marlborough, MA 01752
Jungtinės Amerikos Valstijos

Pirmą kartą registruota: 2014 liepos 1 d.
Peržiūros data: 2020 birželio 1 d.

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