

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

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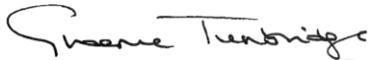
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withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from 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.,



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
<b>CLEARSIGN II Amplifier</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Diagnostic Sterile Cables</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>Fixed Curve Diagnostic Catheters (diagnostic mapping, pacing, and recording catheters)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 646195, 26 May 2024, 2797
<b>LABSYSTEM PRO EP Recording System</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>LABSYSTEM PRO EP Review Workstation Software (recording and amplifier systems)</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Rhythmia HDx Mapping System</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Steerable Diagnostic Catheters (diagnostic mapping, pacing, and recording catheters)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 646196, 26 May 2024, 2797
<b>Umbilical Cables</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>APDL Drainage Catheter System</b> <b>Flexima APDL Drainage Catheter System</b> <b>Flexima APDL Drainage Catheter System Kit</b> <b>Flexima APD Drainage Catheter System</b> <b>Flexima APD Drainage Catheter System</b> <b>Flexima Biliary Catheter System</b> <b>Flexima Biliary Catheter System Kit</b> <b>Flexima Biliary Catheter System with Radiopaque Marker</b> <b>Flexima Nephrostomy Catheter System</b> <b>Flexima Nephrostomy Catheter System Kit</b> <b>Flexima QuickStick Drainage Catheter System</b> <b>Flexima Ureteral Stent System</b> <b>Flexima Ureteral Stent System Kit Percuflex</b>	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
<b>Nephroureteral Stent</b> <b>Nephroureteral Stent System</b> <b>Percuflex Nephroureteral Stent</b> <b>Percuflex Ureteral Stent System</b> <b>Percuflex Ureteral Stent System Kit</b> <b>VanSonnenberg Drainage Catheter System</b> <b>vanSonnenberg Sump Sump Catheter System Kit</b> <b>VTC Nephrostomy Catheter System</b> <b>VTC Nephrostomy Catheter System Kit</b>			
<b>AccuStick II, AccuStick Needle</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Amplatz Super Stiff Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616368, 26 May 2024, 2797
<b>AngioJet AVX Thrombectomy Set</b> <b>AngioJet AVX Over-the-Wire Thrombectomy Set</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>AngioJet Solent Dista Thrombectomy Set</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>ANGIOJET SOLENT omni THROMBECTOMY SET,</b> <b>AngioJet SOLENT proxi THROMBECTOMY SET</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>ANGIOJET ULTRA SYSTEM CONSOLE</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>AngioJet Zelante DVT Thrombectomy Set</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Back-up Meier Steerable Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616313, 26 May 2024, 2797
<b>JETSTREAM PVCN100 Console</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>JETSTREAM SC 1.6 Atherectomy Catheter,</b> <b>JETSTREAM SC 1.85 Atherectomy Catheter,</b> <b>(JETSTREAM SC OVER-THE-WIRE Atherectomy Catheter)</b> <b>JETSTREAM XC 2.1/3.0 Atherectomy Catheter,</b>	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
<b>JETSTREAM XC 2.4/3.4 Atherectomy Catheter (JETSTREAM XC OVER-THE-WIRE Atherectomy Catheter)</b>			
<b>Mach1 Guide Catheters</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>NVI Connecting Tube</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>Percufix Catheter Cuff kit</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>Platinum Plus Guidewire, Platinum Plus Glidex Guidewire</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Stainless Steel Guidewire Floppy Radiopaque Tip Nitinol Guidewire Floppy Radiopaque Tip</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Transend Guidewire with ICE Hydrophilic Coating</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Transend Guidewires (includes Transend 0.010 Guide Wires, Transend 300 (ES, Floppy) and Transend EX 0.014)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616358, 26 May 2024, 2797
<b>V-14 Control Wire Guidewire</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>V-18 Control Wire Guidewire</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>LeVeen CoAccess Electrode System, LeVeen CoAccess Introducer Set, LeVeen Needle Electrode, LeVeen SuperSlim Electrode System, Soloist Single Needle Electrode</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>ChoICE Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>ChoICE Magnet Guidewire</b>	Class III - Non-Impl	ChoICE Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>ChoICE PT Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>ChoICE PT Magnet Guidewire</b>	Class III - Non-Impl	ChoICE PT Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>CrossBoss Catheter</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 617066, 26 May 2024, 2797
<b>Expo Angiographic Catheter</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616318, 26 May 2024, 2797

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<b>Fighter Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>Hornet 10 Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>Hornet 14 Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>Hornet Guidewire (Sentai)</b>	Class III - Non-Impl	JUDO 1 Guidewire	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>Impulse Angiographic Catheters</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616317, 26 May 2024, 2797
<b>JUDO 1 Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>JUDO 3 Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>JUDO 6 Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>Luge Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>Luge Magnet Guidewire</b>	Class III - Non-Impl	Luge Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>Mach I Guide Catheter</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616319, 26 May 2024, 2797
<b>Mailman Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>Mailman Magnet Guidewire</b>	Class III - Non-Impl	Mailman Guidewire	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>Marvel Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>PT Graphix Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>PT Graphix Magnet</b>	Class III - Non-Impl	PT Graphix	CE 616288, 26 May 2024, 2797 CE 616303, 26 May 2024, 2797
<b>PT2 Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616304, 26 May 2024, 2797
<b>RunWay Guide Catheter</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 616319, 26 May 2024, 2797
<b>Samurai Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>Samurai RC Guidewire (Sentai)</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 642447, 26 May 2024, 2797
<b>Stingray Extension Wire</b>	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
<b>Stingray Guidewire</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 617065, 26 May 2024, 2797
<b>Stingray LP Catheter</b>	Class III - Non-Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 617065, 26 May 2024, 2797
<b>Stretch Extension Wire</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>WATCHDOG Hemostasis Valve Kit</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>WATCHDOG™ Hemostasis Valve</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Navigator HD Ureteral Access Sheath Set and Navigator Ureteral Access Sheath Set</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Stone Cone Nitinol Urological Retrieval Coil</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>AdVance™ XP Male Sling System</b>	Class III - Impl	Not applicable	CE 616288, 26 May 2024, 2797
<b>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</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>AMS 700 Inflatable Penile Prosthesis</b>	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
<b>AMS 700 Inflatable Penile Prosthesis with IZ</b>	Class III - Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 698551, 26 May 2024, 2797
<b>AMS 700 Accessory Kit</b>	Class IIB- Impl	Not applicable	CE 616288, 26 May 2024, 2797
<b>AMS 800 Artfical Urinary Sphincter</b>	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
<b>AMS 800 Artfical Urinary Sphincter with IZ</b>	Class III - Impl	Not applicable	CE 616288, 26 May 2024, 2797 CE 698552, 26 May 2024, 2797
<b>AMS Disposal Dilator</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Capio SLIM Suture Capturing Device</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Piranha Ureteroscopic Biopsy Forceps</b>	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
<b>Tactra Malleable Penile Prosthesis</b>	Class II B - Impl	Not applicable	CE 616288, 26 May 2024, 2797
<b>Sensor Nitinol Wire with Hydrophilic Tip</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>ZeroTip Nitinol Stone Retrieval Basket Escape Nitinol Stone Retrieval Basket OptiFlex Nitinol Stone Retrieval Basket Dakota Nitinol Stone Retrieval Basket with OpenSure Handle</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Amplatz Renal Dilator + Set Amplatz Renal Sheath + Set</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Amplatz Super Stiff Guidewire</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Ureteral Catheter Flexible Tip Open End Ureteral Catheter Set, Ureteral Catheter Open End Ureteral Catheter Set, Ureteral Catheter Pigtail Ureteral Catheter Set</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>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</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Urolok™ II Adaptor</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Zebra Guidewires</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>SAPS CF Single Action Pumping System Continuous Flow Single Action Pumping System (irrigation)</b>	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
<b>Nottingham One-Step Hydrogel Coated Ureteral Dilator Ureteral Dilatation System</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Gemini Paired Wire Helical Stone Retrieval Basket Segura Hemisphere Stone Retrieval Basket</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>TLA Introducer Needle and Sheath Set NaviGuide Percutaneous Access Needles Percutaneous Access Needle Percutaneous Access Needle with Echogenic Tip</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Captiflex Single-Use Polypectomy Snare</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Captivator II Single-Use Polypectomy Snare</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Captivator Single-Use Polypectomy Snare</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Expect Pulmonary Adaptor</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>Gold Probe Bipolar Electrohemostasis Catheters</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Injection Gold Probe Bipolar Electrohemostasis Catheters</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Rotatable Snare</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Sensation™ Short Throw Single-Use Polypectomy Snare</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Speedband™ Superview Super 7 Band Ligator</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>SpyBite Max Biopsy Forceps</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>SpyGlass Retrieval Basket</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>SpyGlass Retrieval Snare</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Ultratome XL Triple Lumen Sphincterotome</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>AutoCap RX Integrated Biopsy Cap Locking device</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797



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<b>Acquire Pulmonary Endobronchial Ultrasound Fine Needle Biopsy Device</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Device</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Captivator™ COLD Single-Use Polypectomy Snare</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Captivator™ EMR device</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Celebrity Cytology Brushes</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>Contour ERCP Cannula</b>	Class I S	Not applicable	CE 616288, 26 May 2024, 2797
<b>CoreDx Pulmonary Mini-Forceps Biopsy Forceps</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Dreamtome RX Sphincterotome</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Dreamwire High Performance Guidewire</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>eXcelon™ Transbronchial Aspiration Needle</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Expect™ Endoscopic Ultrasound Aspiration Needle</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Expect™ Slimline Endoscopic Ultrasound Aspiration Needle</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Hydra Irrigation Tubing System</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Hydra Jagwire High Performance Guidewire</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Hydra Water Bottle Cap System</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Hydratome RX Sphincterotome</b>	Class II B	Not applicable	CE 616288, 26 May 2024, 2797
<b>Interject Injection Therapy Needle Catheter</b>	Class II A	Not applicable	CE 616288, 26 May 2024, 2797
<b>Jagtail High Performance Guidewire Extension</b>	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

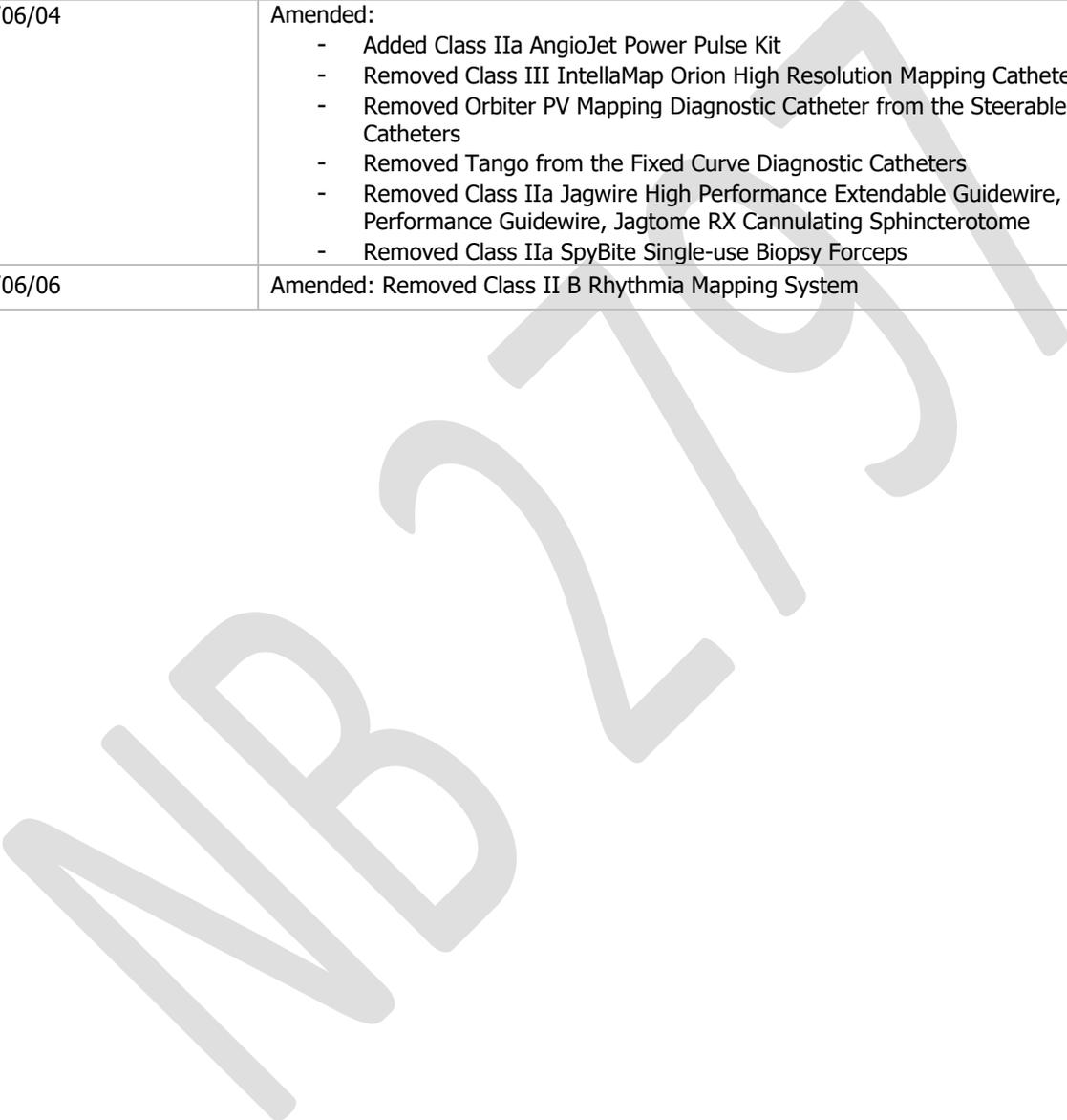
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under 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: <ul style="list-style-type: none"> <li>- Added Class IIa AngioJet Power Pulse Kit</li> <li>- Removed Class III IntellaMap Orion High Resolution Mapping Catheter</li> <li>- Removed Orbiter PV Mapping Diagnostic Catheter from the Steerable Diagnostic Catheters</li> <li>- Removed Tango from the Fixed Curve Diagnostic Catheters</li> <li>- Removed Class IIa Jagwire High Performance Extendable Guidewire, Jagwire High Performance Guidewire, Jagtome RX Cannulating Sphincterotome</li> <li>- Removed Class IIa SpyBite Single-use Biopsy Forceps</li> </ul>
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.

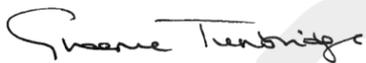
Priemonių, kurioms taikomi pagal Direktyvą 90/385/EEB (toliau – AIMDD) arba Direktyvą 93/42/EEB (toliau – MPD) išduoti sertifikatai, kurių galiojimas baigėsi po 2021 m. gegužės 26 d. ir iki 2023 m. kovo 20

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 nebūtinai notifikuotosios įstaigos dalyvavimas, tačiau pagal MPR jis būtinai (pvz., I klasės priemonėms, kurios laikomos daugkartinio naudojimo chirurginiais instrumentais).

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



Graeme Tunbridge

Vyresnysis pirmininko pavaduotojas, Medicinos priemonių skyrius



**Boston Scientific Corporation**  
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## Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*<sup>1</sup>
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Boston Scientific Corporation
Manufacturer address and contact details	300 Boston Scientific Way Marlborough, MA 01752 USA
Single Registration Number (SRN) (if available)	US-MF-000004702

Authorised Representative name (if applicable)	Boston Scientific Limited
Authorised Representative address and contact details	Ballybrit Business Park Galway IRELAND
Single Registration Number (SRN) (if available)	IE-AR-000003840

Notified body name (if applicable)	DEKRA  <b>X See attached schedule</b>
------------------------------------	---

<sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Notified body number (if applicable)	X See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	X See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	X See attached schedule
End date of extended validity/transition period	X See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>2</sup>
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements: **Not Applicable**

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

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<sup>2</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- 
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

*Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

**X Expired/expires after 20 March 2023:**

*Choose one applicable statement:*

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.**
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

**➤ Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement: **Not Applicable***

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.**
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

Full Company Name: **Boston Scientific Corporation**

Location: **MN, USA**

Name: **Aaron Dunbar**

Title: **Vice President, Quality Systems and Post Market**

Email: **Aaron.Dunbar@bsci.com**

Signature:  \_\_\_\_\_  
Electronically signed by:  
Aaron Dunbar  
Reason: I am the Approver  
Date: Feb 21, 2024 15:56  
CST

Date: 21-Feb-2024

**Schedule of Devices**

The above Manufacturer's Declaration is valid for the following devices:

**Electrophysiology (EP) Products:**

<b>Identification of the device(s)<sup>3</sup></b> (e.g., device name, family/group name device model or catalogue number)	<b>Directive Certificate number(s) to which this confirmation is made (if applicable)</b>	<b>Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)</b>	<b>Notified Body name and number that issued the Directive Certificate (if applicable)</b>	<b>Notified Body name and number where the MDR application was lodged/contract signed (if applicable)</b>	<b>End date of extended validity / transition period</b>	<b>Substitute Device(s) (if applicable)</b>
Dx Sterile Cables - DEKRA	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Rx Sterile Cables - DEKRA	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Blazer Dx-20 Diagnostic Catheter	3812454CE01 3812454DE15	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer II HTD Temperature Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer II Temperature Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer II XP Temperature Ablation Catheter & XP HTD	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer Open-Irrigated Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer Prime XP Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Blazer Prime HTD Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

<sup>3</sup> for devices with AIMDD/IMDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

<b>Identification of the device(s)<sup>3</sup></b> (e.g., device name, family/group name, device model or catalogue number)	<b>Directive Certificate number(s) to which this confirmation is made</b> (if applicable)	<b>Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity</b> (if applicable)	<b>Notified Body name and number that issued the Directive Certificate</b> (if applicable)	<b>Notified Body name and number where the MDR application was lodged/contract signed</b> (if applicable)	<b>End date of extended validity / transition period</b>	<b>Substitute Device(s)</b> (if applicable)
IntellaNav MiFi Open-Irrigated Ablation Catheter	3812454CE01 3812454DE37	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav MiFi XP Temperature Ablation Catheters	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav Open-Irrigated Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav ST Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaNav StablePoint Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaTip MiFi Open-Irrigated Ablation Catheter	3812454CE01 3812454DE37	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
IntellaTip MiFi XP Temperature Ablation Catheter	3812454CE01 3812454DE14	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Irrigation Tubing Set	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
MetriQ Irrigation Tubing Set	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
MetriQ Pump	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Polaris X Steerable Diagnostic Catheter	3812454CE01 3812454DE15	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

**Peripheral Interventions (PI) Products:**

Identification of the device(s) <sup>4</sup> (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
2D Helical-35 Fibered Platinum Coil	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Athletis	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Berenstein & Standard Occlusion Balloon Catheter (IIB)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Carotid Wallstent Monorail Carotid Endoprosthesis	3812454CE01 3812454DE28	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Charger PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Coil Pusher-16	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Contour Embolization Particles	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Coyote Balloon Dilatation Catheters MR & OTW	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-2028	Not applicable
Coyote ES Monorail PTA Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-2028	Not applicable
Coyote ES Over-the-Wire PTA Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-2028	Not applicable
Direxion Torqueable Microcatheter Direxion HI-FLO Torqueable	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

<sup>4</sup> for devices with AIMDD/IMDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Microcatheter Direxion Fathom -16 System Pre-Loaded Torqueable Microcatheter Direxion Transend-14 System Pre-Loaded Torqueable Microcatheter Direxion HI-FLO Fathom-16 System Pre-Loaded Torqueable Microcatheter Direxion HI-FLO Transend-18 System Pre-Loaded Torqueable Microcatheter	3812454CE01 3812454DE38	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Epic Over the Wire Self-Expanding Nitinol Vascular Stent with Delivery System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Equalizer Occlusion Balloon	3812454CE01 3812454DE11	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Express Vascular LD Premounted Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Express Vascular SD Premounted Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Fathom 016 Steerable Guidewire	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Fathom-14 Steerable Guidewire	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Fibered Platinum Coils : VortXTM -18 and VortXTM Diamond-18 Fibered Platinum Coils Complex Helical-18, Figure 8-18,	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Multi-Loop-18, straight-18 Fibered Platinum Coils									
FloSwitch HP High Pressure Flow Control Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-28	DEKRA - 0344	31-Dec-28	Not applicable
Gateway PTA Balloon Catheter (Gateway)	3812454CE01 3812454DE10	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Guider Softip XF Guide Catheter 5FR - 6FR - 7FR - 8FR	3812454CE01 3812454DE02	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
IDC Interlocking Detachable Coils	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Innova Over-The-Wire Self-Expanding Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Interlock - 35 Fibered IDC Occlusion System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Interlock Fibered IDC Occlusion System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Mustang PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-28	DEKRA - 0344	31-Dec-28	Not applicable
OptiCross 35	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-28	DEKRA - 0344	31-Dec-28	Not applicable
Peripheral Cutting Balloon (2cm Peripheral Cutting Balloon )	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-28	DEKRA - 0344	31-Dec-28	Not applicable
Microsurgical Dilatation Device									
Renegade Fiber Braided Microcatheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Renegade Hi-Flo Fathom System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Renegade Hi-Flo Microcatheter Kits	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Renegade Hi-Flo Microcatheter.	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable
Renegade STC-18 Microcatheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	DEKRA - 0344	31-Dec-27	DEKRA - 0344	31-Dec-27	Not applicable

Rubicon Support Catheter 14, 18 & 35	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Sterling Monorail PTA Balloon dilatation catheter	3812454CE01 3812454DE10	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Sterling Over-The-Wire PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Sterling SL Monorail PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Sterling SL Over-The-Wire PTA Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
VortX-35 Fibered Platinum Coil	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary Transhepatic Fully Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary Transhepatic Fully Covered Stent System RMV	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
WallFlex Biliary Transhepatic Partially Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
WallFlex Biliary Transhepatic Uncovered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Wallstent RP Endoprosthesis	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Wallstent-Uni Endoprosthesis IIb	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Wallstent-Uni Endoprosthesis III	3812454CE01 3812454DE25	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
XXL Balloon Dilatation Catheter (Vascular)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Embozene Color-Advanced Microspheres	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
TANDEM Microspheres	3812454CE01 3812454DE44	26 May 2024 11 Mar 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

**Interventional Cardiology (IC) Products:**

Identification of the device(s) <sup>5</sup> (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
OptiCross 6 Coronary Imaging Catheter & OptiCross 6 HD Coronary Imaging Catheter	3812454CE01 3812454DE18	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
OptiCross Coronary Imaging Catheter & OptiCross HD Coronary Imaging Catheter	3812454CE01 3812454DE18	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Comet II Pressure Guidewire	3812454CE01 3812454DE39	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Comet Pressure Guidewire	3812454CE01 3812454DE39	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Comet II Pressure Guidewire
Disposable Pullback Sled	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Emerge MONORAIL PTCA Dilatation Catheter	3812454CE01 3812454DE23	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

<sup>5</sup> for devices with AIMDD/IMDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Emerge Push MONORAIL PTCA Dilatation Catheter									
Emerge OVER-THE-WIRE PTCA Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
Emerge Push OVER-THE-WIRE PTCA Dilatation Catheter	3812454DE23								
Encore 26 Advantage Kit	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable			
Encore 26 Inflation Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable			
Fluid Dock	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable			
GateWay Plus Y-Adapter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable			
Guidezilla II Guide Extension Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
Guidezilla II LONG Guide Extension Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
Mamba and Mamba Flex Microcatheter	3812454CE01 3812454DE42	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
Maverick 2 Monorail PTCA	3812454CE01 3812454DE20	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
MDU5 PLUS Sterile Bag	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable			
NC Emerge PTCA Dilatation Catheter (MONORAIL)	3812454CE01 3812454DE34	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
NC Quantum Apex MONORAIL PTCA Dilatation Catheter	3812454CE01 3812454DE12	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
NC Quantum Apex OVER-THE-WIRE PTCA Dilatation Catheter	3812454CE01 3812454DE12	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			
OptiCross 18 30 MHz Peripheral Imaging Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable			
PROMUS Elite Monorail Everolimus-Eluting Coronary Stent System	3812454CE01 3812454DE43	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable			

Promus PREMIER Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE06	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Promus PREMIER Select MONORAIL Everolimus-Eluting Platinum Chromium Stent System	3812454CE01 3812454DE41	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Rotablator Rotational Angioplasty System: Console	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Rotablator RotaWire Guidewire with wireClip Torquer	3812454CE01 3812454DE24	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
RotaLink Advancer Catheter Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
RotaLink Burr Exchangeable Burr Catheter	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
RotaLink Plus Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
ROTAPRO Rotational Angioplasty System: Console	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
ROTAPRO Advancer Burr Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
ROTAPRO Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device	3812454CE01 3812454DE26	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Synergy MEGATRON MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE32	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Synergy XD MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE46	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Threader Monorail Micro-Dilatation Catheter	3812454CE01 3812454DE33	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Threader Over the Wire Micro-Dilatation Catheter	3812454CE01 3812454DE33	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Ultra ICE Plus 9 IntraCardiac Echo Catheter	3812454CE01 3812454DE18	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WireClip Torquer	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Wolverine Coronary Cutting Balloon MONORAIL Microsurgical Dilatation Device	3812454CE01 3812454DE40	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
SYNERGY MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System	3812454CE01 3812454DE32	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Synergy XD Everolimus-Eluting Platinum Chromium Coronary Stent System

**Urology and Pelvic Health (Uro) Products:**

<b>Identification of the device(s)<sup>6</sup></b> (e.g., device name, family/group name device model or catalogue number)	<b>Directive Certificate number(s) to which this confirmation is made</b> (if applicable)	<b>Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity</b> (if applicable)	<b>Notified Body name and number that issued the Directive Certificate</b> (if applicable)	<b>Notified Body name and number where the MDR application was lodged/contract signed</b> (if applicable)	<b>End date of extended validity / transition period</b>	<b>Substitute Device(s)</b> (if applicable)
UroMax Ultra Balloon Dilation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Encore 26 Inflation Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Gateway Advantage Y-Adapter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Nephromax High Pressure Nephrostomy Balloon Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Occluder Occlusion Balloon Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
SpaceOAR	3812454CE01 3812454DE47	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
SpaceOAR Vue	3812454CE01 3812454DE47	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

<sup>6</sup> for devices with AIMDD/IMDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

**Endoscopy (Endo) Products:**

Identification of the device(s) <sup>7</sup> (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
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	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

<sup>7</sup> for devices with AIMDD/IMDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Alliance II Integrated Inflation System (60ml Syringe/Gauge assembly)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Hurricane Rapid Exchange Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE RX Biliary Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE Wireguided Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE Fixed Wire Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE PRO Wireguided Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
CRE Pulmonary Balloon Dilatation Catheter	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Encore 26 Inflation device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Extractor Pro Retrieval Balloon Catheter (RX, RX-S, XL)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Resolution 360 Clip Resolution Clip Device	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Resolution 360 Ultra Clip	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Rigiflex II Single Use Achalasia Balloon Dilator	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-28	Not applicable
Ultraflex Esophageal Stent System (Covered & Uncovered) - Large Esophageal & Esophageal NG	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Non sterile	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Ultraflex Tracheobronchial Stent System (Gen II - with green retention suture) - Sterile	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Fully Covered	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Fully Covered RMV	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Partially Covered	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Biliary RX Stent System Uncovered	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Enteral Stent With Anchor lock delivery System (Colonic)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Enteral Stent With Anchor lock delivery System (Duodenal)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Fully Covered RMV Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Fully Covered RMV Stent System Longer Loop	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Fully Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Esophageal Partially Covered Stent System	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
WallFlex Soft Enteral Stent With Anchor lock delivery System (Colonic)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable

Manufacturer's Declaration

WallFlex Soft Enteral Stent With Anchor lock delivery System (Duodenal)	3812454CE01	26 May 2024	DEKRA - 0344	DEKRA - 0344	31-Dec-27	Not applicable
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# Manufacturer Declaration\_DEKRA

Final Audit Report

2024-02-21

Created:	2024-02-21
By:	Mary Fretland (Mary.Fretland@bsci.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAABAK3TAJ8zr-f2MFNkaECiMHmoXn7XPMrHL
Number of Documents:	1
Document page count:	19
Number of supporting files:	0
Supporting files page count:	0

## "Manufacturer Declaration\_DEKRA" History

-  Document created by Mary Fretland (Mary.Fretland@bsci.com)  
2024-02-21 - 7:57:12 PM GMT
-  Document emailed to Aaron Dunbar (Aaron.Dunbar@bsci.com) for signature  
2024-02-21 - 7:59:42 PM GMT
-  Email viewed by Aaron Dunbar (Aaron.Dunbar@bsci.com)  
2024-02-21 - 9:43:30 PM GMT
-  Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.  
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2024-02-21 - 9:51:47 PM GMT
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Challenge: The user completed the signing ceremony.  
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-  Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user completed the signing ceremony.  
2024-02-21 - 9:54:09 PM GMT
-  Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user opened the agreement.  
2024-02-21 - 9:56:11 PM GMT

✔ Aaron Dunbar (Aaron.Dunbar@bsci.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2024-02-21 - 9:56:44 PM GMT

✔ Aaron Dunbar (Aaron.Dunbar@bsci.com) has agreed to the terms of use and to do business electronically with Boston Scientific

2024-02-21 - 9:56:45 PM GMT

✔ Document e-signed by Aaron Dunbar (Aaron.Dunbar@bsci.com)

Signing reason: I am the Approver

Signature Date: 2024-02-21 - 9:56:45 PM GMT - Time Source: server

✔ Agreement completed.

2024-02-21 - 9:56:45 PM GMT



**Boston Scientific Corporation**  
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Marlborough, MA 01752  
(508) 683-4000  
[www.bostonscientific.com](http://www.bostonscientific.com)

## Gamintojo deklaracija

dėl Reglamento (ES) 2023/607, kuriuo iš dalies keičiamos reglamentų (ES) 2017/745 ir (ES) 2017/746 nuostatos dėl pereinamojo laikotarpio nuostatų, susijusių su tam tikromis medicinos priemonėmis ir *in vitro* diagnostikos medicinos priemonėmis, konkrečiai

- atsižvelgiant į sertifikatų, išduotų pagal Tarybos direktyvą 90/385/EEB dėl aktyviųjų implantuojamųjų medicinos prietaisų (AIMDD) arba Tarybos direktyvą 93/42/EEB dėl medicinos priemonių (MPD) (direktyvos sertifikatai), galiojimą; *ir (arba)*<sup>1</sup>
- atsižvelgiant į priemonių ir jų gamintojo atitiktį tęstinio pateikimo rinkai ir naudojimo sąlygoms.

Gamintojo pavadinimas	„Boston Scientific Corporation“
Gamintojo adresas ir kontaktiniai duomenys	300 Boston Scientific Way Marlborough, MA 01752 JAV
Bendrasis registracijos numeris (SRN) (jei yra)	US-MF-000004702

Įgaliotojo atstovo pavadinimas (jei taikoma)	„Boston Scientific Limited“
Įgaliotojo atstovo adresas ir kontaktiniai duomenys	Ballybrit Business Park Galway AIRIJA
Bendrasis registracijos numeris (SRN) (jei yra)	IE-AR-000003840

Notifikuotosios įstaigos pavadinimas (jei taikoma)	„DEKRA“  X Žr. pridedamą sąrašą.
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<sup>1</sup> Pirmasis punktas netaikomas priemonių, kurių atitikties vertinimo procedūroje pagal MDD nebūtina dalyvauti notifikuotajai įstaiagai, kurių atitikties deklaracija buvo parengta iki 2021 m. gegužės 26 d. ir kurių atitikties vertinimo procedūroje pagal šį reglamentą būtina dalyvauti notifikuotajai įstaiagai, atveju.

Notifikuotosios įstaigos numeris (jei taikoma)	X Žr. pridedamą sąrašą.
Direktyvos sertifikato (-ų) numeris (-iai), kuriems taikomas šis patvirtinimas (jei taikoma)	X Žr. pridedamą sąrašą.
Pradinė galiojimo data, nurodyta direktyvos sertifikate iki galiojimo pratęsimo (jei taikoma)	X Žr. pridedamą sąrašą.
Pratęsto galiojimo / pereinamojo laikotarpio pabaigos data	X Žr. pridedamą sąrašą.

Mes, kaip gamintojas, pareiškiame, kad prisiimame visą atsakomybę:

- už pirmiau nurodyto **direktyvos sertifikato** (arba žr. pridedamą sąrašą, jei sertifikatų yra keli) teisinio galiojimo pratęsimo sąlygų laikymąsi, kaip numatyta MPR 120 straipsnio 2 dalyje; *ir (arba)*<sup>2</sup>
- už pridedamame sąrašė nurodytas priemones, ir mes, kaip jų gamintojas, užtikriname MPR 120.3c straipsnyje išvardytų tęstinio pateikimo rinkai ir naudojimo sąlygų laikymąsi;

t. y. vykdome šias sąlygas:

> **Direktyvos sertifikatas (-ai)**, kaip nurodyta pirmiau arba pridėtame sąrašė:

- Direktyvos sertifikatas (-ai), taikomas (-i) sąrašė nurodytoms priemonėms, buvo išduotas (-i) po 2017 m. gegužės 25 d., galiojo 2021 m. gegužės 26 d. ir nebuvo vėliau atšauktas (-i).

*Pasirinkite taikytinus teiginius: Netaikoma*

- Nustojo galioti *iki* 2023 m. kovo 20 d.:
  - Prieš pradinę galiojimo pabaigos datą, nurodytą direktyvos sertifikate (-uose), mes ir notifikuotoji įstaiga sudarėme rašytinį (-ius) susitarimą (-us) pagal šio reglamento VII priedo 4.3 skirsnio antrą punktą dėl priemonių, kurioms taikomas (-i) sertifikatas (-ai), kurio (-ių) galiojimas pasibaigė, arba priemonių, skirtų pakeisti tas priemones, atitikties vertinimo (-ų); arba
  - Kompetentinga institucija suteikė leidimą nukrypti nuo taikytinos atitikties vertinimo procedūros pagal MPR 59 straipsnio 1 dalį (gali būti pateikta pateikus prašymą); arba

<sup>2</sup> Pirmasis punktas netaikomas priemonių, kurių atitikties vertinimo procedūroje pagal MDD nebūtina dalyvauti notifikuotajai įstaiagai, kurių atitikties deklaracija buvo parengta iki 2021 m. gegužės 26 d. ir kurių atitikties vertinimo procedūroje pagal šį reglamentą būtina dalyvauti notifikuotajai įstaiagai, atveju.

- Kompetentinga institucija pagal MPR 97 straipsnio 1 dalį pareikalavo, kad gamintojas atliktų taikomą atitikties vertinimo procedūrą (gali būti pateikta pateikus prašymą).

*Pasirinkite vieną iš toliau nurodytų teiginių tik tuo atveju, jei kompetentinga institucija taiko nukrypti leidžiančią nuostatą pagal 59 straipsnio 1 dalį arba nustatė reikalavimus pagal 97 straipsnio 1 dalį:*

- Oficialią (-as) paraišką (-as) notifikuotajai įstaigai pagal MPR VII priedo 4.3 skirsnio pirmą punktą dėl atitikties įvertinimo pateikėme arba pateiksime ne vėliau kaip 2024 m. gegužės 26 d. dėl pridedamame sąraše nurodytų priemonių arba pakaitinių priemonių, o iki 2024 m. rugsėjo 26 d. pagal MPR VII priedo 4.3 skirsnio antrą punktą bus sudarytas (-i) rašytinis (-iai) susitarimas (-ai).
- Iki 2024 m. gegužės 26 d. neketiname pateikti paraiškos dėl atitikties vertinimo, todėl pereinamasis laikotarpis baigsis 2024 m. gegužės 26 d.

**X Nustoją (nustos) galioti po 2023 m. kovo 20 d:**

*Pasirinkite vieną taikytiną teiginį:*

- Oficialią (-as) paraišką (-as) notifikuotajai įstaigai pagal MPR VII priedo 4.3 skirsnio pirmą punktą dėl atitikties įvertinimo pateikėme arba pateiksime ne vėliau kaip 2024 m. gegužės 26 d. dėl pridedamame sąraše nurodytų priemonių arba pakaitinių priemonių, o iki 2024 m. rugsėjo 26 d. pagal MPR VII priedo 4.3 skirsnio antrą punktą bus sudarytas (-i) rašytinis (-iai) susitarimas (-ai).**
- Iki 2024 m. gegužės 26 d. neketiname pateikti paraiškos dėl atitikties vertinimo, todėl pereinamasis laikotarpis baigsis 2024 m. gegužės 26 d.

**> Neklasifikuojamos priemonės**

Priemonių, kurių atitikties vertinimo procedūroje pagal MPD nebūtina dalyvauti notifikuotajai įstaigai, kurių atitikties deklaracija buvo parengta iki 2021 m. gegužės 26 d. ir kurių atitikties vertinimo procedūroje pagal šį reglamentą būtina dalyvauti notifikuotajai įstaigai, atveju:

*Pasirinkite taikytinus teiginius: **Netaikoma***

- Oficialią (-as) paraišką (-as) notifikuotajai įstaigai pagal MPR VII priedo 4.3 skirsnio pirmą punktą dėl atitikties įvertinimo pateikėme arba pateiksime ne vėliau kaip 2024 m. gegužės 26 d. dėl pridedamame sąraše nurodytų priemonių arba pakaitinių priemonių, o iki 2024 m. rugsėjo 26 d. pagal MPR VII priedo 4.3 skirsnio antrą punktą bus sudarytas (-i) rašytinis (-iai) susitarimas (-ai).
- Iki 2024 m. gegužės 26 d. neketiname pateikti paraiškos dėl atitikties vertinimo, todėl pereinamasis laikotarpis baigsis 2024 m. gegužės 26 d.

> **Kokybės vadybos sistema (KVS)**

*Pasirinkite taikytinus teiginius:*

- Ne vėliau kaip 2024 m. gegužės 26 d. bus įdiegta KVS pagal MPR 10 straipsnio 9 dalį.
- Įdiegta KVS pagal MPR 10 straipsnio 9 dalį.**
- Notifikuotoji įstaiga išdavė pridedamą sertifikatą, patvirtinantį MPR reikalavimus atitinkančią KVS.

> **Pridedamame sąrašė nurodytos priemonės**

- Priemonės toliau atitinka AIMDD arba MPD reikalavimus.
- Konstrukcijos ir numatytos paskirties esminių pakeitimų nėra.
- Priemonės nekelia nepriimtinos rizikos pacientų, naudotojų ar kitų asmenų sveikatai ar saugai arba kitiems visuomenės sveikatos apsaugos aspektams.

**Pasirašyta gamintojo vardu:**

Įmonės pavadinimas: „**Boston Scientific Corporation**“

Vieta: **MN, JAV**

Vardas ir pavardė: **Aaron Dunbar**

Pareigos: **Pirmininko padėjėjas, Kokybės sistemų ir rinkos priežiūros skyrius**

El. paštas: [Aaron.Dunbar@bsci.com](mailto:Aaron.Dunbar@bsci.com)

Parašas:



*Elektroniniu būdu pasirašė:  
Aaron Dunbar  
Priežastis: esu tvirtintojas  
Data: 2024 m. vasario 21 d.  
15:56 CST*

**Data:** 2024 m. vasario 21 d.

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

**Your ref.** NoC 2023-080, 2024-034  
**Our ref.** MED/24-3835256 Rev3  
**Tel.** +31 88 96 83 009  
**Fax** +31 88 96 83 100  
**E-mail** [medical.nl@dekra.com](mailto: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,



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 Endoprosthesis	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

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
Microcatheter			
ELUVIA Over-The-Wire Drug-Eluting Vascular Stent System	Class III - Impl	Not applicable	3812454CE01 3812454DE38
Epic Over the Wire Self-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
Truselect	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

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

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
(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 <u>NOT</u> 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.

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

**Jūsų nuor. Nr.** NoC 2023-080, 2024-034  
**Mūsų nuor. Nr.** MED/24-3835256 Rev3  
**Tel.** +31 88 96 83 009  
**Faks.** +31 88 96 83 100  
**El. paštas** medical.nl@dekra.com

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:

Boston Scientific Corporation  
300 Boston Scientific Way  
Marlborough, MA 01752  
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 nepriėmė 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, sraigčiai, 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 nebūtinai notifikuotosios įstaigos dalyvavimas, tačiau pagal MPR jis būtinai (pvz., I klasės priemonėms, kurios laikomos daugkartinio naudojimo chirurginiais instrumentais).

Notifikuotosios įstaigos vardu,



Amy Gravley,  
Projektų vadovė

# 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

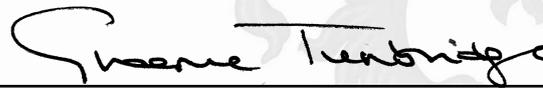
Holds Certificate Number:

**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:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-05-08

Latest Revision Date: 2023-08-29

Effective Date: 2023-09-02

Expiry Date: 2026-09-01



Page: 1 of 9

...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

Latest Revision Date: 2023-08-29

Effective Date: 2023-09-02

Expiry Date: 2026-09-01

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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

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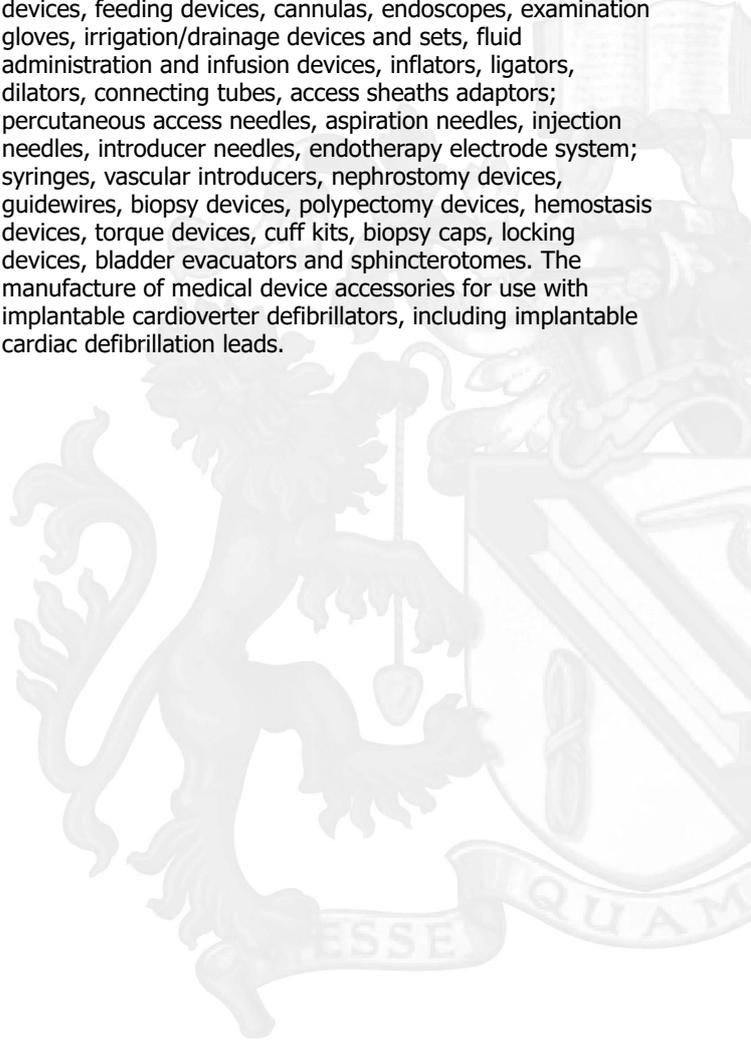
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Location

Boston Scientific Corporation  
780 Brookside Drive  
Spencer  
Indiana  
47460  
USA

Registered Activities

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

Latest Revision Date: 2023-08-29

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Certificate No: **MD 670368**

Location

Boston Scientific Ltd.  
2 Paget Rd  
Unit #2  
Brampton  
Ontario  
L6T 5G3  
Canada

Registered Activities

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

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Certificate No: **MD 670368**

Location

Boston Scientific Corporation  
100 Boston Scientific Way  
Marlborough  
Massachusetts  
01752  
USA

Registered Activities

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

Latest Revision Date: 2023-08-29

Effective Date: 2023-09-02

Expiry Date: 2026-09-01

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

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

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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

Latest Revision Date: 2023-08-29

Effective Date: 2023-09-02

Expiry Date: 2026-09-01

Page: 8 of 9

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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

Latest Revision Date: 2023-08-29

Effective Date: 2023-09-02

Expiry Date: 2026-09-01

Page: 9 of 9

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# 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

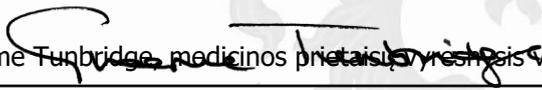
Turi sertifikatą, kurio numeris:

**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:

  
Graeme Tunbridge, medicinos prietaisų tyrimų viceprezidentas

Pradinė registracijos data: 2017-05-08

Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02

Galiojimo pabaigos data: 2026-09-01

Lapas: 1 iš 9



...making excellence a habit.™

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BSI Group Assurance Limited, registruota Anglijoje numeriu 7805321 adresu 389 Chiswick High Road, Londonas, W4 4AL,  
JK. BSI įmonių grupės narys.

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. Ultragarso 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

Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02

Galiojimo pabaigos data: 2026-09-01

Lapas: 2 iš 9

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JK. BSI įmonių grupės narys.

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
<u>Boston Scientific Corporation</u> 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 trombo 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.
<u>Boston Scientific Corporation</u> 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.
<u>Boston Scientific Corporation</u> 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

Lapas: 3 iš 9

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JK. BSI įmonių grupės narys.

Sertifikatas nr.: **MD 670368**

**Vieta**

**Boston Scientific Corporation**  
780 Brookside Drive  
Spencer  
Indiana  
47460  
JAV

**Registruotos veiklos**

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 apvaskalų 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

Lapas: 4 iš 9

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JK. BSI įmonių grupės narys.

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
<b>Boston Scientific Ltd.</b> 2 Paget Rd Unit #2 Brampton Ontario L6T 5G3 Kanada	<b>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 siurbiai, skysčių administravimo, užpildymo ir infuzijos prietaisai, pripūtimo įtaisai, ligatoriai, dilatatoriai, jungiamieji vamzdeliai, prieigos apvalkalai, vamzdelių rinkiniai, adapteriai, kairiojo prieširdžio priedo (LAA) uždarymo įtaisai ir pagalbinių 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, manžėčių 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, sulaukymui 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).</b>

Pradinė registracijos data: 2017-05-08

Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02

Galiojimo pabaigos data: 2026-09-01

Lapas: 5 iš 9

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JK. BSI įmonių grupės narys.

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
<u>Boston Scientific Corporation</u> 100 Boston Scientific Way Marlborough Massachusetts 01752 JAV	<u>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 sistemos ir priedai.</u>



Pradinė registracijos data: 2017-05-08

Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02

Galiojimo pabaigos data: 2026-09-01

Lapas: 6 iš 9

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Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
<u>Boston Scientific Corporation</u> 4100 Hamline Ave. N. St. Paul Minnesota 55112 JAV	<u>Medicinos prietaisų projektavimas ir tobulinimas</u> 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 siurbiai 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.
<u>Boston Scientific Technology &amp; Engineering Services Pvt. Ltd.</u> 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, implantuojamųjų 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

Lapas: 7 iš 9

Šis sertifikatas išduotas elektroniniu būdu, lieka BSI nuosavybe ir yra saistomas sutarties sąlygų. Elektroninio sertifikato galiojimas gali būti patvirtintas [internetu](#). Spausdintos kopijos gali būti validuojamos adresu [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Informacija ir kontaktai: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel.: + 44 345 080 9000  
BSI Group Assurance Limited, registruota Anglijoje numeriu 7805321 adresu 389 Chiswick High Road, Londonas, W4 4AL,  
JK. BSI įmonių grupės narys.

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 stimulatoriaus ryšio sąsajos stimuliavimo sistemos analizatorius, stimulatorius, 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

Naujausios revizijos data: 2023-08-29

Įsigaliojimo data: 2023-09-02

Galiojimo pabaigos data: 2026-09-01

Lapas: 8 iš 9

Šis sertifikatas išduotas elektroniniu būdu, lieka BSI nuosavybe ir yra saistomas sutarties sąlygų. Elektroninio sertifikato galiojimas gali būti patvirtintas [internetu](#).  
Spausdintos kopijos gali būti validuojamos adresu [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Informacija ir kontaktai: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel.: + 44 345 080 9000  
BSI Group Assurance Limited, registruota Anglijoje numeriu 7805321 adresu 389 Chiswick High Road, Londonas, W4 4AL,  
JK. BSI įmonių grupės narys.

Sertifikatas nr.: **MD 670368**

Vieta	Registruotos veiklos
<b>Boston Scientific Technology &amp; Engineering Services Pvt. Ltd.</b> 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 priegigos kateterius, mikrokaterius, vielinius kreiptuvus, hemostazės prietaisus, trombų kateterio prietaisus, perkutaninės priegigos 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.
<b>Boston Scientific International Sdn. Bhd</b> 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.
<b>Boston Scientific Corporation</b> 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

Lapas: 9 iš 9

Šis sertifikatas išduotas elektroniniu būdu, lieka BSI nuosavybe ir yra saistomas sutarties sąlygų. Elektroninio sertifikato galiojimas gali būti patvirtintas [internetu](#).  
Spausdintos kopijos gali būti validuojamos adresu [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Informacija ir kontaktai: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel.: + 44 345 080 9000  
BSI Group Assurance Limited, registruota Anglijoje numeriu 7805321 adresu 389 Chiswick High Road, Londonas, W4 4AL,  
JK. BSI įmonių grupės narys.

# EC CERTIFICATE

Number: 3812454CE01

1/2

## 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), electro-surgical, 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:

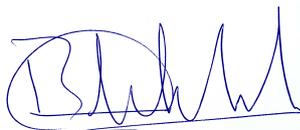
# 0344

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.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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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

2/2

## 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.

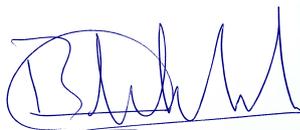
This certificate is valid until: **26 May 2024**

Issued for the first time: 1 July 2014

Revised: 21 December 2018

Reissued: 30 April 2020

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of a stylized, cursive script.

B.T.M. Holtus  
Managing Director

A blue ink signature of J.A. van Vugt, consisting of a stylized, cursive script.

J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: **3812454CE01**

1/4

## 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:

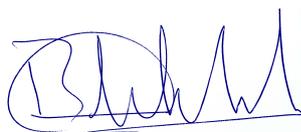
### **Boston Scientific Corporation**

**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 Coyal 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.



**B.T.M. Holtus**  
Managing Director



**J.A. van Vugt**  
Certification Manager

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# ADDENDUM

Belonging to certificate: **3812454CE01**

2/4

## 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.

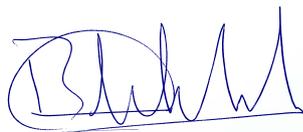
Issued to:

**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

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B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: **3812454CE01**

3/4

## 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.

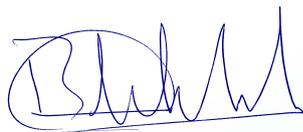
Issued to:

**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 LTD 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		

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: **3812454CE01**

4/4

## 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

DEKRA Certification B.V.



**B.T.M. Holtus**  
Managing Director



**J.A. van Vugt**  
Certification Manager

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# „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  
Vykdomasios direktorius

/parašas/

J.A. van Vugt  
Sertifikavimo vadybininkas

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“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.

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B.T.M. Holtus  
Vykdomasis direktorius

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J.A. van Vugt  
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Tel. +31 88 96 83000 Faks. +31 88 96 83100 www.dekra-product-safety.com Įmonės registracijos numeris 09085396

# „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, endoskopinėms 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

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## PRIEDAS

Priklausantis sertifikatui: 3812454CE01

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## CE ATITIKTIES ŽENKLINIMAS MEDICINOS PRIETAISAI

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

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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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Priklausantis sertifikatui: 3812454CE01

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## CE ATITIKTIES ŽENKLINIMAS MEDICINOS PRIETAISAI

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

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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		

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Priklausantis sertifikatui: **3812454CE01**

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## **CE ATITIKTIES ŽENKLINIMAS MEDICINOS PRIETAISAI**

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

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Pirmą kartą registruota: 2014 liepos 1 d.

Peržiūros data: 2020 birželio 1 d.

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