

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-05-08

Latest Revision Date: 2021-02-26

Effective Date: 2020-09-02

Expiry Date: 2023-09-01

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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. Manufacturing activities associated with radio frequency and cryo ablation devices and accessories. These 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.

External instrumentation for implantable cardiac monitors, implantable cardiac pulse generators and implantable cardioverter defibrillators including implantable cardiac pacing and defibrillation leads. Design, development, manufacturing, 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 of minimally invasive biologic heart valves and raw material patches from biologic origin.

Servicing of medical device electronic systems associated with diagnostics, monitoring and therapy. Kitting, labeling, and distribution of ultrasound imaging systems accessories.

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

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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. Manufacturing 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 and distribution 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. Manufacturing activities associated with radio frequency ablation devices and accessories. These products include: biliary stents, ureteral stents, drainage catheters, introducer catheters, urological catheters, percutaneous catheters, biliary devices, 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.
Boston Scientific Corporation 300 Boston Scientific Way Marlborough Massachusetts 01752 USA	Administrative Activities.

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Certificate No: **MD 670368**

Location

Boston Scientific Corporation
780 Brookside Drive
Spencer
Indiana
47460
USA

Registered Activities

Manufacture and distribution 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.

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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.
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Certificate No: **MD 670368**

Location

Boston Scientific Ltd.
6430 Vipond Drive
Mississauga
Ontario
L5T 1W8
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.

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

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Boston Scientific Corporation 100 Boston Scientific Way Marlborough Massachusetts 01752 USA	Design and development of devices in the areas of Gastroenterology, Nephrology, Gynecology, Urology, Endoscopy, Biliary and General Surgery (including Minimally Invasive Surgical Procedures). These products include: biliary stents, ureteral stents, pancreatic stents, drainage catheters, introducer catheters, urological catheters, percutaneous catheters and guide catheters, biliary devices, retrieval devices, feeding devices, cannulas, endoscopes, irrigation/drainage devices and sets, fluid administration and infusion devices, inflators, ligators, dilators, connecting tubes, adaptors, access sheaths, percutaneous access needles, aspiration needles, injection needles, endotherapy electrode systems, fiber optic laser delivery devices, sutures and suturing devices, nephrostomy devices, guidewires, biopsy devices, surgical mesh, polypectomy devices, hemostasis devices, torque devices, endoscopic valves, endoscope channel support kits, biopsy caps, locking devices, bladder evacuators and sphincterotomes, penile prosthesis implants for continence, accessories and surgical tools.
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 servicing of cardiac ablation systems inclusive of accessory devices. Distribution of urological devices such as generators and software for generators. Manufacture 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, servicing and distribution of atherectomy angioplasty devices systems and accessories. Manufacturing, servicing and distribution to endoscope systems and accessories. Kitting, labeling, and distribution of ultrasound imaging systems accessories. Servicing of medical device electronic systems associated with diagnostics, monitoring, and therapy.

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Location	Registered Activities
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). These products include Introducer sheath and kits, Vascular access catheter, microcatheters, Guide wires, Hemostasis devices, Thrombus catheter devices, Percutaneous access needles, 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.
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. Manufacture of minimally invasive biologic heart valves and raw material patches from biologic origin.
Boston Scientific Corporation 10700 Bren Road West Minnetonka Minnesota 55343 USA	Design, development, and manufacture of penile prostheses, implants for continence with and without antibacterial treatment and associated accessories, and surgical tools.
Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland	Design development and manufacture of penile prosthesis. Servicing of medical device electronic systems associated with diagnostics, monitoring and therapy.
Boston Scientific Corporation 1745 Copperhill Parkway, Suite 1 Santa Rosa California 95403 USA	Design, development, manufacture and distribution of embolic protection devices.

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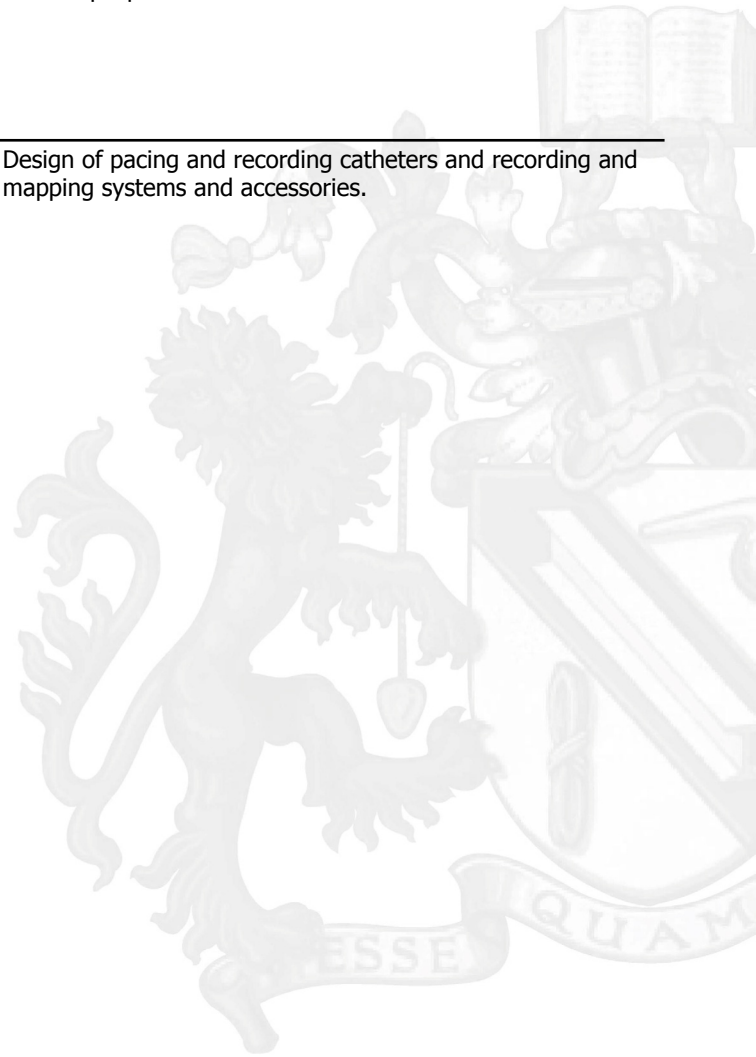
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Location	Registered Activities
Boston Scientific Corporation 3636 N Laughlin Road Santa Rosa California 95403 USA	Design, development, manufacture and distribution of embolic protection devices.
Boston Scientific Corporation 11810 Wills Road Alpharetta Georgia 30009 USA	Manufacture and distribution of endoscope accessories and endoscopic procedure kits.
Boston Scientific Corporation 125 Cambridgepark Drive Cambridge Massachusetts 02140 USA	Design of pacing and recording catheters and recording and mapping systems and accessories.



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