

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: 2023-12-21

Effective Date: 2023-09-02

Expiry Date: 2026-09-01



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...making excellence a habit.™

Certificate No:

MD 670368

Registered Scope:

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

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

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

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

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

Original Registration Date: 2017-05-08

Effective Date: 2023-09-02

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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.

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Certificate No: **MD 670368**

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.

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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.

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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.

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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.

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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.

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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 10700 Xylon Avenue North Brooklyn Park Minnesota 55445 USA	The manufacture (acceptance activities) and distribution of components and devices in the areas of neuromodulation, cardiovascular (including Cardiovascular Interventions), Peripheral (including Peripheral Interventions), Electrosurgical Applications (including Electrophysiology), Urology, and Endoscopy.
Boston Scientific Corporation 309 Waverley Oaks Rd Waltham Massachusetts 02452 USA	Design of pacing and recording catheters and recording and mapping systems and accessories.

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