

# CERTIFICATE

Number: 3818536

The management system of:

## Boston Scientific Corporation

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

Including the implementation meets the requirements of the standard:

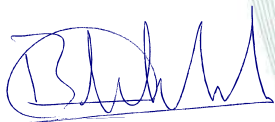
## EN ISO 13485:2016

### Scope:

Design, development, manufacturing, including ethylene oxide sterilization, installation, servicing, warehousing and distribution of medical devices for minimally invasive biliary, cardiovascular (including cardiovascular interventions), electrophysiology, electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) urology and oncology procedures: adapters, atherectomy angioplasty systems, atherotomy devices, balloon catheters, drug coated balloon catheters, biologic heart valve replacements and delivery systems, bronchial thermoplasty catheters and footswitches, cables, cardiac ablation catheters, catheters, connecting tubes, cuff kits, drainage catheters, drug eluting stents and delivery catheter systems, electrophysiology equipment, electrosurgical instruments and generators, embolic protection systems, embolization devices, embolization coils, embolic microspheres, fiducial markers, endoscopic instruments, endoscope systems, endotherapy electrode system, entry needles, extension wires, fiberoptic laser delivery unit, fluid circulation pumps, fluid filling devices, footswitches, generators, guide catheters, guidewires, heated fluid hyperthermia systems accessories, haemostasis devices, hydrogel polymer devices, inflation devices, introducer catheters, left atrial appendage (LAA) closure devices and accessory devices, microcatheters, nephrostomy devices, pacing and recording catheters, pericardiocentesis kits, power cords, radio frequency ablation system, cryoablation system and instruments, retrieval sheaths, rotating haemostatic valves, shaping mandrels, solid state medical laser systems, stents and delivery catheter systems, stents and delivery catheter systems including electrocautery tip, endoscopic valves, endoscope channel support kits, stopcock, surgical meshes, tissue and thrombus removal devices, torque devices, tubing sets, ultrasound imaging systems, vascular dilators, terminal liquid sterilization services, laboratory testing of biological indicators. The provision of Ethylene Oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and ISO 11135:2014.

Certificate expiry date: 23 March 2024  
Certificate effective date: 13 September 2023  
Certified since: 23 March 2018

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M. McKenzie  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM 1/3

to Certificate: **3818536**

Concerning the Management System of:

## Boston Scientific Corporation

List of certified locations:

Location Code	Company name / address	Scope
BHM	ACURATE Indústria e Comércio LTDA BHM Site (Belo Horizonte Site) Avenida General David Sarnoff, 3445 Lote 02 – Quadra 31A Cidade Industrial Contagem/MG – Brazil	Manufacture and Sterilization of porcine percutaneous aortic valve assembled on stent, and laboratory testing
COR	Boston Scientific Limited Business & Technology Park Model Farm Rd Cork, Ireland	Manufacturing of medical devices for minimally invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures: adapters, atherectomy angioplasty system, balloon catheters, bronchial thermoplasty catheters and footswitches, embolization coils, fiducial markers, embolization devices, extension wires, fibreoptic laser delivery devices, guidewires, hydrogel polymer devices, inflation devices, microcatheters, renal denervation catheters, rotating haemostatic valves, shaping mandrels, endoscopic valves, endoscope channel support kits and stopcock.
COV	Boston Scientific Corporation 8 Industrial Drive Coventry, RI 02816 USA	Laboratory testing of Biological Indicators. Ethylene Oxide Sterilization of Medical Devices and Laboratory Testing of Biological Indicators. The provision of Ethylene Oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and ISO 11135:2014.



# ADDENDUM 2/3

to Certificate: **3818536**

Concerning the Management System of:

## Boston Scientific Corporation

List of certified locations: continued

Location Code	Company name / address	Scope
GAL	Boston Scientific Limited Ballybrit Business Park Galway, Ireland	Design, development and manufacturing of medical devices for minimally invasive biliary, cardiovascular (including cardiovascular interventions), endoscopy, gastroenterology, nephrology, peripheral (including peripheral interventions) and urology procedures: atherotome devices, balloon catheters, drug coated balloon catheters, biologic heart valve replacements and delivery systems, catheters, drug eluting stents and delivery catheter systems, left atrial appendage (LAA) closure devices and accessory devices and stents and delivery catheter systems including electrocautery tip. Ethylene Oxide Sterilization of Medical Devices. The provision of Ethylene Oxide sterilization services fulfilling applicable quality management system requirements within EN ISO 11135:2014 and ISO 11135:2014.
KER	Boston Scientific International BV Vestastraat 6, 6468 EX Kerkrade, the Netherlands	Manufacture, Installation and Servicing, Warehousing and Distribution (see scope listing on page 1)
MAR	Boston Scientific Corporation 100 Boston Scientific Way Marlborough, MA 01752 USA	Design, development and manufacturing of medical devices for minimally invasive biliary, electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology and urology procedures: balloon catheters, bronchial thermoplasty catheters and footswitches, fiberoptic laser delivery unit, footswitches, generators, heated fluid hyperthermia systems, haemostasis devices, hydrogel polymer devices, power cords, and surgical meshes. Design and development of solid state medical laser systems. Design and development of fiber optic laser delivery devices. Design and development of inflation devices, stents and delivery catheter systems including electrocautery tip and stopcock. Design and development of fiducial markers.



# ADDENDUM 3/3

to Certificate: **3818536**

Concerning the Management System of:

## Boston Scientific Corporation

List of certified locations: continued

Location Code	Company name / address	Scope
MG2	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA	Design, development and manufacturing of medical devices for minimally invasive biliary, cardiovascular (including cardiovascular interventions), neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures: adapters, balloon catheters, drug coated balloon catheters, catheters, drainage catheters, drug eluting stents and delivery catheter systems, electrosurgical instruments and generators, endotherapy electrode system, entry needles, guide catheters, guidewires, introducer catheters, left atrial appendage (LAA) closure devices and accessory devices, radiofrequency ablation system, retrieval sheaths, stents and delivery catheter systems, tissue and thrombus removal devices, torque devices and vascular dilators. Component manufacturing for minimally invasive biologic heart valve replacements and delivery systems. Design and development of atherectomy angioplasty system, atherectomy devices, embolic protection systems, embolization devices, extension wires, inflation devices, microcatheters, stopcock. Design and development of ultrasound imaging systems, embolic microspheres and cryoablation system and instruments.
QUI	Boston Scientific Corporation Marina Bay Customer Fulfillment Center 500 Commander Shea Blvd Quincy, MA 02171 USA	Manufacturing, Warehousing and Distribution (see scope listing on page 1)

Addendum expiry date: 23 March 2024

Addendum effective date: 13 September 2023