

bsi.



By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 616288

Issued To:

**Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-06-30**

Date: **2019-10-02**

Expiry Date: **2021-09-25**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

Certificate No: CE 616288

Certificate Scope:

Design, Development, and Manufacturing of Guidewires, Angiographic Catheters, Microcatheters, Guide Catheters, Radio Frequency Ablation Catheters, Medical Laser Systems and single-use and reusable Fiber Optic Laser Delivery Devices, Diagnostic Mapping, Pacing, and Recording Catheters, Mapping Systems, Electrosurgical Electrodes, and Generators, Recording and Amplifier Systems, Including Software, Percutaneous Catheters, Stents, Needles, Dilators, Accessories, Introducer Catheter, Drainage and Urological Catheters, Urological Irrigation, Surgical Meshes, Biliary Devices, Biopsy Devices, Retrieval Devices, Nephrostomy Devices, Feeding Devices, Ligators, Polypectomy Devices, Hemostasis Devices, Sphinctertomes, Suturing Devices, Endoscopes, Endoscopic Drainage Stents, Delivery Systems and Endoscopic Access Devices, endoscopic irrigation, endoscope channel support kits, endotherapy electrode systems, Atrial Appendage Closure Devices and Sterile Delivery Systems, and minimally invasive tissue and thrombus removal devices.

Design, development, manufacturing, and sterilization of penile prostheses with and without antibacterial treatment and associated accessories, implants for continence with and without antibacterial treatment and associated accessories and sterile surgical tools.

Those aspects of Annex II related to securing and maintaining the sterility in the manufacture of the ACUITY LDS Accessories, Cannulas, Fluid Administration Devices, Exchange Devices, Umbilical Cables, Cables and Accessories, Retrieval devices, endoscopic valves, endoscope channel support kits, biopsy devices. Those aspects of Annex II related to maintaining the metrology function of inflators and accessory devices.

First Issued: **2014-06-30**

Date: **2019-10-02**

Expiry Date: **2021-09-25**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Date	Reference Number	Action
30 June 2014	8181988	First issue with Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, Massachusetts 01752, USA as Legal Manufacturer. Mirror certificate to CE 552701.
15 October 2014	8198968	Addition of Synergy Health in Costa Rica as significant subcontractor for ETO sterilization.
21 January 2015	8246376	Notified Body transfer of various families of devices primarily in the endoscopic and urological areas associated with the Spencer, IN and the Coyo, Costa Rica facilities. Update to the certificate scope to add these device families. Addition of various significant subcontractors involved in the manufacturing and sterilization.
27 March 2015	8296210	Addition of Endoscopes, Biliary Devices, and Inflation Devices to the scope of the certification. Addition of Sterigenics in Queensbury, NY and updates to the services supplied by Sterigenics in Charlotte, NC and the Boston Scientific Heredia facility.
08 May 2015	8321233	"Manufacture" to Maple Grove location; remove activity "Design" from Plymouth location. Add Bard Electrophysiology, Lowell, as subcontractor for Design. Add Creation Technologies as subcontractor for Manufacture. Add Dedicated Computing as Crucial Supplier. Add "Recording & Amplifier Systems, Including Software" to certification scope.

...making excellence a habit.™

Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, 389, Market Street, London EC1R 3BG, UK
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.



By Royal Charter

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 616288**
Date: **2019-10-02**
Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Date	Reference Number	Action
25 June 2015	8359186	Notified Body Transfer of Entry Needles, Torque Vise, and Vascular Dilators into BSI as part of existing certificate scope.
23 July 2015	8365588	Addition of tissue and thrombus removal devices to the certification scope for the Bayer devices as part of the quality system integration. Addition of significant subcontractor Minnetronix for the manufacture of consoles.
27 August 2015	8411080	Extension to scope to add Diagnostic Mapping, Pacing, and Recording Catheters and Umbilical Cable and the related significant subcontractors
07 October 2015	8419835	Update to scope to remove 'Magnetic' to include other types of Exchange Devices. Addition of significant subcontractor FMD. Co., Ltd. for the services of design and manufacture.
11 November 2015	8426230	Addition of Boston Scientific location in Galway, Ireland as a significant subcontractor for manufacturing.
27 November 2015	8431360	Addition of BSC Minneapolis sites for Design and Manufacture as part of quality system integration of tissue and thrombus removal devices.
22 January 2016	8373818	Update to scope to add 'Cables' as part of Legal Manufacturing change for the Bard EP integration. Addition of significant subcontractor TechDevice Costa Rica for the services of manufacture.

...making excellence a habit.™

Page 2 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Date	Reference Number	Action
08 April 2016	8482253	Addition of subcontractor Availmed S.A. de C.V., Col. Cd. Industrial (Otay) for the manufacture of Expo and Impulse angiographic catheters.
22 April 2016	8520699	Removal of ATEK Medical from list of subcontractors, name change of subcontractor from Accellent to Venusa de Mexico, and the addition of Boston Scientific Limited for the services of manufacture and labeling.
01 June 2016	8373832	Addition of Bard Glens Falls Operation as subcontractor for Manufacture.
03 August 2016	8555778	Extension to Scope to include Mapping Systems, and addition of subcontractors BSC St. Paul for Design and Manufacture and Creation Technologies for Manufacture.
05 September 2016	8591247	Addition of endoscopic drainage stents, delivery systems and endoscopic access devices to the scope to include the AXIOS devices.
22 September 2016	8590168	Certificate Renewal. Remove Boston Scientific 8880 & 9055 Evergreen Blvd. locations from listed subcontractors. Added the following subcontractors for Manufacture: Brivant Ltd., Galway, Ireland; Lake Region Medical, New Ross, Ireland; and, Lake Region Medical, Penang, Malaysia.

...making excellence a habit.™

Page 3 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Date	Reference Number	Action
17 March 2017	8693310	Transfer of Advance XP, Auriga XL, and Vela XL and updates to significant subcontractors.
25 July 2017	8743945 8752585	Addition of subcontractor ELECTRON BEAM SDN. BHD (Malaysia) for the service of E Beam sterilization for the Radial Jaw 4 Biopsy Forceps. Extension of scope to include fiber optic laser delivery devices and addition of related subcontractors (Light Guide Optics, Latvia and Medicoplast, Germany).
22 December 2017	8871846	Remove Sterigenics Queensbury NY. Add subcontractor Boston Scientific, Gurgaon, for the service of Design. Add subcontractor Boston Scientific, Pulau Pinang, for the service of Manufacture.
07 February 2018	8727903	Sterilization optimization changes: Synergy Health Chamber 3 Costa Rica, Chamber 8 and 9 Tullamore, Chamber 1, 2, 3, 5, 6, 7, 8, 9 and 10 Coventry. Use of new PCD in Teleflex TFX cycle at Synergy Health Tullamore. Corrected text error in Light Guide Optics address, name change Vanusa de Mexico and removal of Creation technologies North Fraser Way, Burnaby subcontractors.

...making excellence a habit.™

Page 4 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Date	Reference Number	Action
06 June 2018	8940301	Remove Synergy Health AST, Venlo and remove Boston Scientific, Plymouth MN location; correct typo in Venusa De Mexico S. de R.L. de C.V. address; replace Steris Isomedix Services name with Isomedix Operations, Inc. for all locations; correct Synergy Health AST, SRL address; and, update FMD. Co., Ltd. Address
17 December 2018	9659112	Extension of scope to include penile prostheses, implants for continence, endoscopic irrigation, endoscope channel support kits. Extension to scope of Annex II section to add retrieval devices, endoscopic valves, endoscope channel support kits. Add Biomerics for service of Manufacture. Add EirMed for service of Manufacture. Add Jiangsu Jianyu for service of Manufacture. Add Goals sterilization for service of ETO sterilization.
5 March 2019	8250540	Traceable to NB 0086.
Current	9769496	Update scope to include endotherpahy electrode system and microcatheters; Add Statice and BSC Bren Road subcontractors; change Biomerics, LLC address; Add Biopsy Devices to ... securing and maintaining sterility... section. Removal of BSC Fremont, Brivant, Medicoplast, and Dedicated Computing LLC as subcontractors/crucial suppliers.

...making excellence a habit.™

Page 5 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Subcontractor:	Service(s) supplied
Availmed S.A. de C.V. C. Industrial Lt. 001 Mz. 105 No 20905 Int. A Col Cd. Industrial Tijuana Baja California C.P. 22444 Mexico	Manufacture
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior B1,C1, E1, E2, F2, G1 (Local A,B,C,G,H) La Mesa Tijuana C.P. 22116 Mexico	Manufacture
Bard Glens Falls Operation 289 Bay Road Queensbury New York 12804 USA	Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Subcontractor:	Service(s) supplied
Biomerics, LLC 6030 W Harold Gatty Drive Salt Lake City UT 84116 USA	Manufacture
Boston Scientific Corporation 100 Boston Scientific Way Marlborough MA 01752 USA	Design
Boston Scientific Corporation 125 Cambridgepark Drive Cambridge MA 02140 USA	Design

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 616288**
 Date: **2019-10-02**
 Issued To: **Boston Scientific Corporation**
300 Boston Scientific Way
Marlborough
Massachusetts
01752
USA

Subcontractor:	Service(s) supplied
Boston Scientific Corporation 150 Baytech Drive San Jose CA 95134 USA	Labelling Manufacture Packaging
Boston Scientific Corporation 10700 Bren Road W Minnetonka MN 55343 USA	Design Development Manufacture
Boston Scientific Corporation 2546 First Street Propark, El Coyol, Alajuela Costa Rica	Manufacture

...making excellence a habit.™