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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**
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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: **2021-04-30** Expiry Date: **2024-05-26**

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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, Minimally Invasive Tissue and Thrombus Removal Devices, and Embolic Protection Devices.
Design, development, manufacturing, and sterilization of penile prostheses with and without antibacterial treatment and associated accessories, urinary implants for incontinence 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, Biopsy Cap Locking Devices. Those aspects of Annex II related to maintaining the metrology function of inflators and accessory devices.

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Number	Device Name	Intended Purpose
Class III		
N/A	AMS 800 Artificial Urinary Sphincter with InhibiZone	CE 698552
N/A	AMS 700 Inflatable Penile Prosthesis with InhibiZone	CE 698551
N/A	IntellaMap Orion High Resolution Mapping Catheter	CE 640895
N/A	Viking Diagnostic Catheters	CE 646195
N/A	Tango Diagnostic Catheters	CE 646195
N/A	Woven Diagnostic Catheters	CE 646195
N/A	Dynamic Tip Diagnostic Catheters	CE 646196
N/A	EP XT Diagnostic Catheters	CE 646196
N/A	Dynamic XT Diagnostic Catheters	CE 646196
N/A	Orbiter PV Diagnostic Catheters	CE 646196
N/A	ChoICE, ChoICE PT, PT Graphix, Mailman, Luge and ACUITY Guide Wires	CE 616303
N/A	CrossBoss Catheter	CE 617066
N/A	Stingray LP Catheter and Stingray Guidewires and Stingray Extension Wire	CE 617065
N/A	Impulse Angiographic Catheters	CE 616317
N/A	Expo Angiographic Catheters	CE 616318
N/A	Mach 1 and RunWay Guide Catheters	CE 616319
N/A	Sentai Guidewire Family	CE 642447
N/A	PT2 Guide Wire	CE 616304

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Number	Device Name	Intended Purpose
Class III		
N/A	WATCHMAN LAA Closure Technology	CE 617064
N/A	Cerebral Embolic Protection Filter Device	CE 717743
N/A	ACUITY Lead Delivery Systems	CE 616361
N/A	Imager II Angiographic Catheter	CE 616308
N/A	Back-Up Meier Steerable Guidewire	CE 616313
N/A	Transend 0.010 Guidewire with ICE Hydrophilic Coating	CE 616358
N/A	Transend 300 Guidewire with ICE Hydrophilic Coating	CE 616358
N/A	Transend EX Guidewire with ICE Hydrophilic Coating	CE 616358
N/A	Amplatz Super Stiff Guidewire	CE 616368
N/A	AngioJet Spiroflex Monorail Thrombectomy Set	CE 644639
N/A	AngioJet Spiroflex VG Monorail Thrombectomy Set	CE 644639
N/A	AngioJet XMI Over-The-Wire Thrombectomy Set	CE 644639
N/A	AngioJet PE Catheter Over-the-Wire Thrombectomy Set	CE 644641
N/A	SAVION DLVR Guidewire with ICE Hydrophilic Coating	CE 693662
N/A	SAVION FLX Guidewire with ICE Hydrophilic Coating	CE 693662

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Class IIb		
GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
64464 35419 64697 62495	EndoVive Standard PEG Kit EndoVive One Step Button Low Profile PEG Kit Accessories: EndoVive C-Clamp EndoVive Round Bolster EndoVive Low Profile Replacement Button Gastrostomy Tube EndoVive Y-Port Feeding Adapter EndoVive Button Right Angle Feeding Set EndoVive Button Bolus Feeding Set EndoVive Button Decompression Tube	EndoVive Standard PEG Kit is indicated for enteral nutrition directly into the stomach in both pediatric and adult patients who are unable to consume nutrition by conventional means. EndoVive One Step Button Low Profile PEG Kit and EndoVive Low Profile Replacement Button Gastrostomy Tube are intended to provide nutrition to a patient directly into the stomach through a stoma. They are indicated for use on patients who are unable to consume nutrition by conventional means. EndoVive Y-Port Feeding Adapter; EndoVive Button Right Angle Feeding Set and EndoVive Button Bolus Feeding Set are intended to provide nutrition to a patient directly into the stomach through a gastrostomy tube. They are indicated for use on patients who are unable to consume nutrition by conventional means. EndoVive Button Decompression Tube is intended to provide stomach decompression through a gastrostomy tube. It is indicated for use on patients who require enteral feeding as a means of nutritional support.

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Class IIb		
GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
64464 35419 64700 62495	EndoVive Standard PEG Kit (with ENFit Connector) EndoVive One Step Button Low Profile PEG Kit (with ENFit Connector) Accessories: EndoVive C-Clamp EndoVive Round Bolster EndoVive Low Profile Replacement Button Gastrostomy Tube (with ENFit Connector) EndoVive Y-Port Feeding Adapter (with ENFit Connector) EndoVive Button Right Angle Feeding Set (with ENFit Connector) EndoVive Button Bolus Feeding Set (with ENFit Connector) EndoVive Button Decompression Tube (with ENFit Connector)	EndoVive Standard PEG Kit is indicated for enteral nutrition directly into the stomach in both pediatric and adult patients who are unable to consume nutrition by conventional means. EndoVive One Step Button Low Profile PEG Kit and EndoVive Low Profile Replacement Button Gastrostomy Tube are intended to provide nutrition to a patient directly into the stomach through a stoma. They are indicated for use on patients who are unable to consume nutrition by conventional means. EndoVive Y-Port Feeding Adapter; EndoVive Button Right Angle Feeding Set and EndoVive Button Bolus Feeding Set are intended to provide nutrition to a patient directly into the stomach through a gastrostomy tube. They are indicated for use on patients who are unable to consume nutrition by conventional means. EndoVive Button Decompression Tube is intended to provide stomach decompression through a gastrostomy tube. It is indicated for use on patients who require enteral feeding as a means of nutritional support.
47656	EndoVive 3-Port Through-the-PEG Jejunal Feeding Tube Kit	is intended to provide enteral access for decompression and delivery of nutrition and/or medication.

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GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
43764 46689	Advanix Biliary Stent with NaviFlex RX Delivery System Advanix Biliary Stent NaviFlex RX Delivery System	is intended for delivery of the stent to the biliary tract for drainage of the bile ducts for splinting or a bile duct during healing, or for providing bile duct patency in a stricture past a stone.
43764 46689	Flexima Biliary Stent with Delivery System RX Biliary Stent with RX Delivery System C-Flex Biliary Stent Percuflex Biliary Stent Percuflex Biliary Stent with Introducer Kit Biliary Stent Introducer	Flexima Biliary Stent with Delivery System & RX Biliary Stent with RX Delivery System: is intended for delivery of the stent to the biliary tract for drainage of the bile ducts for splinting or a bile duct during healing, or for providing bile duct patency in a stricture past a stone. C-Flex Biliary Stent, Percuflex Biliary Stent, Percuflex Biliary Stent with Introducer Kit and Biliary Stent Introducer: is intended for use in the treatment of biliary strictures.
42701 46689	Advanix Pancreatic Stent Advanix Pancreatic Stent Kit NaviFlex RX Pusher NaviFlex Pusher Long Wire Pusher NaviFlex RX Pancreatic Stent Delivery System	is intended for delivery of the stent to the pancreatic duct (PD): • Used to drain pancreatic duct
43566	AXIOS Stent and Delivery System	is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or a walled-off necrosis with ≥ 70% fluid content or the biliary tract.

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GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
62611	Hot AXIOS Stent and Electrocautery-Enhanced Delivery System	The Hot AXIOS Stent and Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst, walled-off necrosis (≥70% fluid content) or the biliary tract. The Hot AXIOS 15mm x15mm Stent and Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or walled-off necrosis (≥70% fluid content).
57944	Habib EndoHPB Bipolar Radiofrequency Catheter	is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts. The Habib EndoHPB Catheter is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear occluded stent.
11490 58739	Rezum Generator Rezum Delivery Device Kit for BPH	The Rezum System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia (BPH). It is indicated for men with a prostate volume ≥ 30 cm3. The Rezum System is also indicated for treatment of prostates with hyperplasia of the central zone and/or a median lobe.

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GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
10735	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 Nephrostomy Catheter Kit Percutaneous Access Sets	Percuflex Locking Loop Nephrostomy Catheter: This Nephrostomy Catheter is intended to establish percutaneous nephrostomy access and is indicated for the following: Diagnostic Indications: • Antegrade pyelography • Pressure/perfusion study (Whitaker test) Therapeutic Indications: • Nephrostomy catheter drainage • Perfusion chemolysis of renal stones • Post-percutaneous nephrolithotomy • Post-percutaneous resection and coagulation of urothelial tumors Percuflex Locking Loop All Purpose Drainage Catheter with Fader Tip: The All Purpose Drainage Catheter is intended to establish percutaneous nephrostomy access and is indicated for the following: Diagnostic Indications: • Antegrade pyelography • Pressure/perfusion study (Whitaker test) Therapeutic Indications: • Nephrostomy catheter drainage • Perfusion chemolysis of renal stones • Post-percutaneous nephrolithotomy • Post-percutaneous resection and coagulation of urothelial tumors Percuflex Locking Loop Nephrostomy Catheter with Fader Tip: The Nephrostomy Catheter is intended to establish percutaneous nephrostomy and is indicated in the following: Indications For Use Diagnostic Indications: • Antegrade pyelography • Pressure/perfusion study (Whitaker test)

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		Therapeutic Indications: • Nephrostomy catheter drainage • Post-percutaneous nepholithotomy • Post-percutaneous resection and coagulation of urothelial tumors Percutaneous Access Set: Percutaneous Access Set is intended to establish percutaneous nephrostomy access and is indicated for the following: Diagnostic Indications: • Antegrade pyelography • Pressure/perfusion study (Whitaker test) Therapeutic Indications: • Nephrostomy catheter drainage • Perfusion chemolysis of renal stones • Post-percutaneous nephrolithotomy • Post-percutaneous resection and coagulation of urothelial tumors Percuflex Combination Stent/Nephrostomy Catheter: This catheter/stent is intended for use in percutaneous drainage to facilitate drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent.

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GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
10735	Jinro Pigtail Nephrostomy Catheter Kit Jinro Pigtail Nephrostomy Catheter Malecot Nephrostomy Catheter Set Re-Entry Malecot Catheters Set	Jinro Pigtail Nephrostomy Catheter: The Jinro Pigtail Nephrostomy Catheter Kit and replacement catheters are intended to establish percutaneous nephrostomy access and is indicated for the following: Diagnostic Indications: • Antegrade pyelography • Pressure/perfusion study (Whitaker test) Therapeutic Indications: • Nephrostomy catheter drainage • Perfusion chemolysis of renal stones • Post-percutaneous nephrolithotomy • Post-percutaneous resection and coagulation of urothelial tumors Malecot and Re-Entry Malecot Catheter Set: The Malecot Nephrostomy Catheter Set is intended to establish percutaneous nephrostomy drainage and is indicated for the following: Diagnostic Indications: • Antegrade pyelography • Pressure/perfusion study (Whitaker test) Therapeutic Indications: • Nephrostomy catheter drainage • Perfusion chemolysis of renal stones • Post-percutaneous nephrolithotomy • Post-Percutaneous resection and coagulation of urothelial tumors

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GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
58005	Mardis Soft Ureteral Stent Set Mardis Soft Ureteral Stent Percuflex Urinary Diversion Stent Set Retromax Plus Endopyelotomy Stent Stretch VL Flexima Ureteral Stent Stretch VL Variable Length Flexima Stent Set	Mardis Soft Ureteral Stent and Stent Sets: The Mardis Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician. Percuflex Urinary Diversion Stent (Open and Closed): For drainage following percutaneous, endoscopic, or operative procedures. Retromax Plus Ureteral Stent: Some of the indications for placement of a Retromax Plus Stent are: • Extrinsic compression of ureter • Ureteral incision • Ureteropelvic junction incision • Stricture dilatation Stretch VL Flexima Ureteral Stent and Stent Set: Some of the indications for placement of a ureteral stent are: • Extrinsic compression of ureter • Ureteral obstruction • Ureteral trauma • Ureteral manipulation • Preparation for ureteral manipulation • Assistance with stone fragment passage

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Class IIb		
GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
58005	Percuflex Ureteral Stent Percuflex Plus Ureteral Stent Contour Ureteral Stent Contour VL Variable Length Ureteral Stent Contour VL Variable Length Ureteral Stent Set Ascerta Ureteral Stent Ascerta VL Ureteral Stent Contour Injection Ureteral Stent Set Contour VL Injection Ureteral Stent Set Tria Soft Ureteral Stent Tria Firm Ureteral Stent Contour VL SureDrive Steerable Ureteral Stent Set Percuflex Plus SureDrive Steerable Ureteral Stent Set	Ascerta and Ascerta VL : The ureteral stents are intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically, or during an open surgical procedure. Tria Firm Ureteral Stent and Tria Soft Ureteral Stent: The Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician Contour VL: Some of the indications for placement of a ureteral stent are: • Extrinsic compression of ureter • Ureteral obstruction • Ureteral trauma • Ureteral manipulation • Preparation for ureteral manipulation • Assistance with stone fragment passage Contour Injection Stent /Contour VL Injection Stent: The Ureteral Injection Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically. Additionally, the Ureteral Injection Stent is intended to inject contrast and saline into the renal collecting system. The Ureteral Injection Stent is indicated for use with urological procedures and/or conditions such as: • Pre-ESWL • Post-ESWL • Ureteral stone obstruction • Post-ureteroscopy • UPJ obstruction

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58005		• Ureteral trauma • Ureteral stricture • Ureteral carcinoma • Retroperitoneal fibrosis • Endopyelotomy • Pyelotomy • Nephrolithotomy • Ureterolithotomy Contour, Percuflex,Percuflex Plus, Contour VL SureDrive Steerable Ureteral Stent Set, Percuflex Plus SureDrive Steerable Ureteral Stent Set:The Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician.

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58005	Polaris Ultra Ureteral Stent Polaris Loop Ureteral Stent	The stents are intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically or during an open surgical procedure by a trained physician.
60786	AdVance XP Male Sling System	The AdVance XP Male Sling System is intended for the treatment of male stress urinary incontinence (SUI) by the placement of a suburethral sling.
36170	Auriga XL 4007 Laser System Auriga 30 Laser System	The Auriga XL holmium Laser is designed for use for invasive and non-invasive Urologic procedures Due to its application adapted parameters, the AURIGA XL Laser Console is qualified for • Lithotripsy • Ablation (dissection, ablation) of soft tissue • Coagulation of soft tissue • Vaporization of liquid The Auriga 30 holmium Laser is designed for use for invasive and non-invasive Urologic procedures. Due to its application adapted parameters, the AURIGA 30 Laser Console is qualified for: • Lithotripsy • Ablation (dissection, ablation) of soft tissue • Coagulation of soft tissue • Vaporization of liquid

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GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
36150	GreenLight XPS Laser System	The GreenLight XPS Laser System is intended for the surgical incision/excision, vaporization, ablation, hemostasis and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.
36250 60787	AMS 700 Inflatable Penile Prosthesis AMS Ambicor Penile Prosthesis AMS 700 Accessory Kit	The AMS 700 Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). The AMS Ambicor Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence).
36251	AMS Spectra Concealable Penile Prosthesis	The AMS Spectra Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery
35280	AMS 800 Artifical Urinary Sphincter AMS 800 Accessory Kit	The AMS 800 AUS is used to treat urinary incontinence due to reduced urethral/bladder outlet resistance (intrinsic sphincter deficiency) in males and females.
36251	Tactra Malleable Penile Prosthesis	The Tactra Penile Prosthesis is a sterile, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in adult males who are determined to be suitable candidates for implantation surgery.

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GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
33586	LABSYSTEM PRO EP Recording System	The LABSYSTEM PRO EP Recording System is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.
32521	CLEARSIGN/CLEARSIGN II Amplifier	The CLEARSIGN/CLEARSIGN II Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the LABSYSTEM PRO EP Recording System) that can record and display the information.
58173	AngioJet Solent Dista OVER-THE-WIRE Thrombectomy Set	The AngioJet Solent Dista Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus from: • upper and lower extremity peripheral arteries and • for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

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58173	AngioJet Solent Omni OVER-THE-WIRE Thrombectomy Set AngioJet Solent Proxi OVER-THE-WIRE Thrombectomy Set	The AngioJet Solent Proxi & Omni Thrombectomy Sets are intended for use with the AngioJet Ultra Console to break apart and remove thrombus from: • upper and lower extremity peripheral arteries ≥ 3.0 mm in diameter, • upper extremity peripheral veins ≥ 3.0 mm in diameter, • ileofemoral and lower extremity veins ≥ 3.0 mm in diameter, • A-V access conduits ≥ 3.0 mm in diameter and • for use with the AngioJet Ultra Power Pulse technique for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.
44307	JETSTREAM SC OVER-THE-WIRE Atherectomy Catheter JETSTREAM XC OVER-THE-WIRE Atherectomy Catheter	The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries, and for the treatment of femoropopliteal in-stent restenosis (ISR) in self-expanding bare metal stents. It is not intended for use in coronary, carotid, iliac or renal vasculature.
58214	AngioJet Ultra 5000A Console Thrombectomy System Console	The AngioJet Ultra Console is intended for use only in conjunction with an AngioJet Thrombectomy Set. Refer to the individual Thrombectomy Set Directions for Use manual for specific clinical applications.

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58173	AngioJet ZelanteDVT OVER-THE WIRE Thrombectomy Set	The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including deep vein thrombus (DVT) from: • Iliofemoral and lower extremity veins ≥ 6.0 mm in diameter and • Upper extremity peripheral veins ≥ 6.0 mm in diameter. The ZelanteDVT Thrombectomy Set is also intended for use with the AngioJet Ultra Power Pulse technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.
58214	JETSTREAM PVCN100 Console	Intended for use in atherectomy of the peripheral vasculature and in breaking apart and removing thrombus from upper and lower extremity peripheral arteries. It is not intended for use in carotid, iliac, or renal vasculature.
37482	Expel Drainage Catheter MPD Drainage Catheter Expel Drainage Catheter with Twist-Loc Hub MPDL Drainage Catheter Expel Drainage Catheter with Twist-Loc Hub MPDL Drainage Catheter Kit Expel Large Capacity Drainage Catheter MPD Large Capacity Drainage Catheter	The drainage catheter is intended to provide percutaneous drainage of abscess fluid collections.

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10735	Malecot Nephrostomy Catheter System Stenting Malecot Nephrostomy Catheter System	The Malecot and the Stenting Malecot Catheters are designed for percutaneous drainage within the renal collecting system while maintaining external access. The Stenting Malecot Nephrostomy Catheter with its extended tip is also designed for internal drainage from the ureteropelvic junction to the bladder.
11490	RF 3000 Radio Frequency Generator	The RF 3000 Radiofrequency Generator is intended for use with separately cleared electrodes for thermal coagulation of soft tissue.
58739	LeVeen Standard Needle Electrode System LeVeen SuperSlim Needle Electrode System LeVeen CoAccess Needle Electrode System CoAccess Introducer Set Soloist Single Needle Electrode	The LeVeen Needle Electrode Family is intended to be used in conjunction with the RF 3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions. These procedures should only be performed by physicians and staff familiar with the equipment and techniques involved.

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Class IIb		
GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
10735 32544 10696 37482	Amplatz Anchor Amplatz Anchor Catheter System APDL Drainage Catheter System Flexima APDL Drainage Catheter System Flexima APDL Drainage Catheter System Kit Flexima APDL Drainage Catheter System Kit with Dissolving Tip Flexima APDL Drainage Catheter System with Dissolving Tip Flexima APD Drainage Catheter System Flexima APD Drainage Catheter System Flexima Biliary Catheter System Flexima Biliary Catheter System Kit Flexima Biliary Catheter System with Dissolving Tip Flexima Biliary Catheter System with Dissolving Tip and Radiopaque Marker Flexima Biliary Catheter System with Radiopaque Marker Flexima Nephrostomy Catheter System Flexima Nephrostomy Catheter System Kit Flexima Nephrostomy Catheter System Kit with Dissolving Tip Flexima Nephrostomy Catheter System with Dissolving Tip Flexima QuickStick Drainage Catheter System	• The Amplatz Anchor Catheter System is intended for use in applications of percutaneous drainage, particularly percutaneous nephrostomy, abscess or external biliary drainage. • To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection. • To provide external and internal percutaneous drainage of the biliary system. • To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.

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Class IIb		
GMDN	**Device or Generic Device Group**	**Intended Purpose per IFU**
10735 32544 10696 37482	Flexima Ureteral Stent System Flexima Ureteral Stent System Kit Percuflex Nephroureteral Stent Nephroureteral Stent System Percuflex Nephroureteral Stent Nephroureteral Stent System with Dissolving Tip Percuflex Ureteral Stent System Percuflex Ureteral Stent System Kit Percuflex Ureteral Stent System with Dissolving Tip VanSonnenberg Drainage Catheter System vanSonnenberg Sump Sump Catheter System Kit vanSonnenberg Sump Sump Catheter System with Dissolving Tip VTC Nephrostomy Catheter System VTC Nephrostomy Catheter System Kit	• The Ureteral Stent is intended to provide drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally. • The Percuflex Nephroureteral Stent is intended for use in Percutaneous Drainage to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent. • The vanSonnenberg Sump Catheter is designed for use as a percutaneously placed drain for intra-abdominal fluid collections. Such conditions include abscesses, cysts, pseudocysts, bilomas, hematomas, seromas, urinomas, or any loculated fluid collection.

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Class IIa		
NBOG	**Device or Device Subcategory**	**N/A**
MD 0102; MDS 7006	Hemostasis devices	N/A
MD 0102; MDS 7006	Needles	N/A
MD 0106: MDS 7006	Needles	N/A
MD 0102; MDS 7006	Endoscopic Irrigation	N/A
MD 0102; MDS 7006	Endoscope Channel Support Kit	N/A
MD 0106: MDS 7006	Biopsy Devices	N/A
MD 1104; MDS 7006	Biopsy Devices	N/A
MD 0106; MDS 7006	Guidewires	N/A
MD 0106; MDS 7006	Drainage Catheters	N/A
MD 1100; MDS 7006	Endoscopes	N/A
MD 0106; MDS 7006	Polypectomy devices	N/A
MD 1104; MDS 7006	Polypectomy devices	N/A
MD 0106	Ligator	N/A
MD 1104; MDS 7006	Sphinctertomes	N/A
MD 0106; MDS 7006	Dilators	N/A
MD 0102; MDS 7006	Irrigation	N/A
MD 0106; MDS 7006	Introducer Catheters	N/A
MD 0106; MDS 7006	Nephrostomy Devices	N/A
MD 0106; MDS 7006	Stents	N/A
MD 0106; MDS 7006	Urological Catheters	N/A
MD 0203; MDS 7006	Urological Catheters	N/A
MD 0106; MDS 7006	Retrieval Devices	N/A
MD 0106; MDS 7006	Suturing Devices	N/A

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Class IIa		
NBOG	**Device or Device Subcategory**	**N/A**
MD 1104; MDS 7006	Endoscopes	N/A
MD 0106; MDS 7006	Single Use and Reusable Fiberoptic Laser Delivery Device	N/A
MD 0106; MDS 7006	Accessories	N/A
MD 0106; MDS 7006	Sterile Tools	N/A
MD 0204; MDS 7006	Surgical Mesh	N/A
MD 1100 MD 1111 MD 1200	Mapping Systems	N/A
MD 1111	Software	N/A
MD 0106; MDS 7006	Introducer	N/A
MD 0106; MDS 7006	Guide Catheters	N/A
MD 0106; MDS 7006	Hemostasis Valves	N/A
MD 0106; MDS 7006	Thrombectomy	N/A
MD 0106; MDS 7006	Introducer Catheters / Guidewires / Accessories	N/A
MD 0106; MDS 7006	Percutaneous Catheters, Stents	N/A

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Class Is		
NBOG	**Device or Device Subcategory**	**N/A**
MD 0102; MDS 7006	Cannulas	N/A
MD 0102; MDS 7006	Fluid Administration devices	N/A
MD 0106; MDS 7006	Endoscopic valves	N/A
MD 0106; MDS 7006	Endoscope Channel Support Kits	N/A
MD 0106; MDS 7006	Retrieval Devices	N/A
MD 0106; MDS 7006	Biopsy Devices	N/A
MD 0106; MDS 7006	Biopsy cap locking devices	N/A
MD 0106; MDS 7006	Accessories	N/A
MD 0100; MDS 7006	Diagnostic Sterile Cables	N/A
MD 0100; MDS 7006	Umbilical Cables	N/A
MD 0106; MDS 7006	Non-active instruments	N/A
MD 0100; MDS 7006	Accessories	N/A

Class Im		
NBOG	**Device or Device Subcategory**	**N/A**
MD 0104	Inflators	N/A

Class Is/Im		
NBOG	**Device or Device Subcategory**	**N/A**
MD 0102; MDS 7006	Accessory Devices	N/A

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Subcontractor:	**Service(s) supplied**
Availmed S.A. de C.V. Ave. Paseo Reforma No. 8950 Interior E2 La Mesa Tijuana Baja California C.P. 22116 Mexico	**Manufacture**
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**
Boston Scientific Corporation Marina Bay Customer Fulfillment Center 500 Commander Shea Blvd Quincy, MA 02171 USA	**Labelling** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Boston Scientific Corporation 10700 Bren Road W Minnetonka MN 55343 USA	**Design** **Development** **Manufacture**
Boston Scientific Corporation 4100 Hamline Avenue North St. Paul MN 55112-5798 USA	**Design** **Manufacture** **Moist Heat Sterilization**
Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica	**Design** **Manufacture**

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Subcontractor:	Service(s) supplied
Boston Scientific Corporation 125 Cambridgepark Drive Cambridge MA 02140 USA	**Design**
Boston Scientific Corporation Two Scimed Place Maple Grove Minnesota 55311 USA	**Design** **Manufacture**
Boston Scientific Corporation 780 Brookside Drive Spencer Indiana 47460 USA	**Manufacture**

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Subcontractor:	Service(s) supplied
Boston Scientific Corporation 100 Boston Scientific Way Marlborough MA 01752 USA	**Design**
Boston Scientific Corporation 150 Baytech Drive San Jose CA 95134 USA	**Labelling** **Manufacture** **Packaging**
Boston Scientific Corporation 2546 First Street Propark, El Coyol, Alajuela Costa Rica	**Manufacture**
Boston Scientific Limited Cashel Road Clonmel Co. Tipperary Ireland	**Design** **Labelling** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Boston Scientific Limited Ballybrit Business Park Galway Ireland	**ETO Sterilization** **EU Representative** **Manufacture**
Boston Scientific Limited Business and Technology Park Model Farm Road Cork Ireland	**Manufacture**
Boston Scientific Medical Device (Malaysia) SDN BHD PMT 741, Persiaran Cassia Selatan 1 Taman Perindustrian Batu Kawan 14110 Bandar Cassia Pulau Pinang Malaysia	**Manufacture**

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Subcontractor:	Service(s) supplied
Boston Scientific Technology & Engineering Services Pvt., Ltd. 3rd Floor, Bestech Business Tower Sector 48 Sohna Road Gurgaon Haryana 122018 India	**Design**
BSC Coventry 8 Industrial Drive Coventry Rhode Island 02816 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
C.R. Bard 289 Bay Road Queensbury New York 12804 USA	**Manufacture**
Cipan-Companhia Industrial Productora de Antibiotics SA 42 Vala Do Carregado Castanheira Do Ribatejo PT-2600-726 Portugal	**Crucial Supplier** **Medicinal Substances**
Creation Technologies LP 8977-8999 Fraserton Court Burnaby British Columbia V5J 5H8 Canada	**Manufacture**

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Subcontractor:	Service(s) supplied
Electron Beam SDN. BHD. Lot 7 Jalan Sungai Pinang 4/3 Taman Perindustrian Pulau Indah (FASA 2) 42920 Port Klang Selangor Malaysia	**Radiation (E Beam Sterilization)**
FMD Co., Ltd. 1-666 Shimoobari Nakashima Komaki Aichi 485-0051 Japan	**Design** **Manufacture**
Goals Sterilization Co., Ltd. East of Renkangtang South of 07 provincial road, Xinfeng Town Nanhu District 314005 Jiaxing, Zhejiang China	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Isomedix Operations Inc North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Jiangsu JianYu Health Medical Co., Ltd. No. 88 Longxi Avenue, Zhulin Town, Jintan District 213241 Changzhou City, Jiangsu Province People's Republic of China	**Manufacture**
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	**Control of Sterilization** **Manufacture**
Lake Region Medical Limited Butlersland New Ross Co. Wexford Ireland	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Lake Region Medical Sdn. Bhd 91- B Lebuhraya Kampung Jawa 11900 Bayan Lepas Penang Malaysia	**Manufacture**
Light Guide Optics International Celtniecibas iela 8 Livani LV-5316 Latvia	**Manufacture** **Packaging**
Lupin Chemicals Limited T-142 M.I.D.C. Tarapur Via Boisar, Maharashtra, 401 506, India	**Crucial Supplier** **Medicinal Substances**

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Subcontractor:	Service(s) supplied
Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern PA 19355 USA	**Manufacture**
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 USA	**Manufacture** **Testing**
Navilyst Medical, Inc. 10 Glens Falls Technical Park Glens Falls NY 12801 USA	**Manufacture**

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Subcontractor:	Service(s) supplied
Nortech Systems, Inc. 925 6th Ave NE Milaca, MN 56353 USA	**Manufacture**
Northern Digital, Inc. (NDI) 103 Randall Drive Waterloo Ontario N2V 1C5 Canada	**Manufacture**
Sanofi S.R.L. Via Angelo Titi, 22/26 Zona ex Punto Franco 72100 Brindisi Italy	**Crucial Supplier** **Medicinal Substances**
Statice 9 rue Thomas Edison, Z1 des Tilleroyes 2500 BESANCON France	**Manufacture**

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Subcontractor:	Service(s) supplied
Stellartech Research Corporation 560 Cottonwood Drive Milpitas California 95035 USA	**Manufacture**
Sterigenics 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**Radiation (Gamma Sterilization)**
Steri-Tek 48225 Lakeview Blvd. Fremont CA 94538 USA	**Radiation (E Beam Sterilization)**

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Subcontractor:	Service(s) supplied
SurModics, Inc 9924 W. 74th Street Eden Prairie Minnesota 55344-3523 USA	**Manufacture**
Synergy Health AST SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone 20102 El Coyol Alajuela Costa Rica	**ETO Sterilization**
Synergy Health AST, LLC 9020 Activity Road, Suite D San Diego California 92126 USA	**Radiation (E Beam Sterilization)**

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Subcontractor:	Service(s) supplied
Synergy Health AST, SRL B16 Street 4; Avenue O El Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	**Radiation (E Beam Sterilization)**
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization** **Radiation (E Beam Sterilization)**
Synergy Health Westport Ltd Lodge Road Westport County Mayo Ireland	**Radiation (Gamma Sterilization)**

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Subcontractor:	Service(s) supplied
Synergy Sterilisation (M) Sdn. Bhd Plot 203, Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**
TechDevice Costa Rica Limitada 400m Este de Holcim, Zona Industrial Flexipark Bodega G6 San Rafael Costa Rica	**Manufacture**
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Venusa de Mexico S. de R.L. de C.V. a Lake Region Medical Company Calle Hertz 1525 Parque Industrial Antonio J. Bermudez Chihuahua 32470 Ciudad Juarez Mexico	**Manufacture**

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Date: **2021-04-30**

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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 Coyol, 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.

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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.

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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.

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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.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616288**

Date: **2021-04-30**

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.
05 March 2019	8250540	Traceable to NB 0086.
02 October 2019	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.

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Date	Reference Number	Action
27 February 2020	3119395	Add embolic protection devices and biopsy locking devices to scope; Change to Bard address to align with ISO cert; Remove Isomedix New Jersey and Sterigenics Willowbrook; Add BSC Quincy for services of labeling and manufacture; Add Claret Medical for services of design and manufacture; Add Jiangsu JianYu for service of manufacture, Add Nortech for service of manufacture; Add Steri-tek for service of E Beam sterilization; Add Synergy Sterilization Malaysia for service of ETO sterilization. Add service of Design to BSC Clonmel location.

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Date	Reference Number	Action
09 October 2020	9774152	Certificate Renewal. Added product tables. Modified the following subcontractors names or addresses to match their ISO certs: Availmed S.A. de C.V., FMD Co., Ltd., Jiangsu Province JianErKang Medical Dressing Co., Ltd., Statice, Synergy Health AST, LLC, TechDevice Costa Rica Limitada, Teleflex Medical. Removed Biomerics, LLC and EirMed subcontractors. Added the following subcontractors to support AMS 700 and AMS 800 devices: Cipan-Companhia Industrial, Lupin Chemicals Limited, Sanofi S.p.A. Change Claret Medical name to Boston Scientific Corporation for Copperhill address. Modify scope for urinary incontinence devices.
29 January 2021	3319554	Add service of ETO sterilization to Boston Scientific Limited, Ballybrit location; Removed service of Gamma Irradation and added E Beam Sterilization for the Synergy Health Ireland, Tullamore location; Removed Synergy Health AST, LLC, Lima Ohio and Jiangsu Provence JianERKang Medical Dressing Co. Ltd as subcontractors.

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Date	Reference Number	Action
30 April 2021	3404103	Intended Purpose updated as per IFU for Percuflex Locking Loop with Fader Tip Drainage Catheter, Percuflex Locking Loop Nephrostomy Catheter, Percuflex Combination Stent/Nephrostomy Catheter, Percuflex Locking Loop with Fader Tip Nephrostomy Catheter, Jinro Pigtail Nephrostomy Catheter, Malecot and Malecot Re-Entry Nephrostomy Catheter, Percutaneous Access Set.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
Date	**Reference Number**	**Action**
20 July 2021	3410324	Change of classification of Savion guidewires from Class III to IIa with cancellation of CE 693662. Updated subcontractor name for Sanofi S.R.L. Added Moist Heat Sterilization to services supplied for Boston Scientific Corporation, St. Paul location. Removed Boston Scientific Corporation, Cooperhill Parkway subcontractor.

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Inspiring trust for a more resilient world.

20 July 2021

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough
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01752
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 616288	93/42/EEC Annex II, Sec 3.2	3410324	1. Removal of Savion Guidewires from the class III device schedule as they are down classified to class IIa with the devices already included in the class IIa device schedule under "guidewires". 2. Update subcontractor name from Sanofi S.p.A. to Sanofi S.R.L. 3. Add the service of "moist heat sterilization" to the BSC St. Paul location 4. Remove the BSC Copperhill Parkway subcontractor.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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