By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 550209**

Issued To: **Spectranetics Corporation**
9965 Federal Drive
Colorado Springs
Colorado
80921
USA

In respect of:

The design, development and manufacture of Laser Medical Devices and their associated Endovascular Laser Atherectomy Catheters, Pacer and Defibrillator Lead Removal Devices (Lead Locking Stylet for lead traction, Lead-removal Sheaths); Crossing/Support/Guiding Catheters for Coronary and/or Peripheral Use; Vascular Occlusion Catheters; Guidewire Guiding Catheter-Retrievers for Peripheral Use; and Accessories (Gauges, Coil Expanders, Tubing Sets and Scissors).

Those aspects of Annex II relating to securing and maintaining sterility in the design and manufacture of TorqMax Sheath Accessory.

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: **2009-05-13** Date: **2021-01-05** Expiry Date: **2024-05-26**

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Supplementary Information to CE 550209

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Number	Device Name	Intended purpose per IFU
Class III		
---	ELCA (0.9mm/ X-80) Laser Sheath and ELCA (OTW/RX) Laser Sheath	See CE 554813
---	Spectranetics Laser Sheath (SLSII and GlideLight)	See CE 554849
---	SightRail Dilator Sheath	See CE 611537
---	TightRail, TightRail Mini, TightRail Sub-C Rotating Dilator Sheaths	See CE 611679
---	Bridge Occlusion Balloon	See CE 650647
---	Quick-Cross, Quick-Cross Extreme, and Quick-Cross Select Support Catheters	See CE 579513
---	VisiSheath Dilator Sheath	See CE 579514

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Number	Device Name	Intended purpose per IFU
Class IIb		
60389	CVX-300 and Phoenix CVX-300 Excimer Laser System	The CVX-300 is used with Spectranetics Laser Catheters (e.g. ELCA, Turbo Elite, and SLS), each covered under their own Technical File or Dossier. The Instructions for Use for the Laser Catheters contain the Indications for each Laser Catheter (which is powered by the CVX-300). The Indications for Use are also provided in the Technical File / Dossier for each of the Spectranetics Laser Catheters.
43229	Turbo-Power Laser Atherectomy Catheter	Turbo Power is indicated for laser atherectomy of de novo or restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in stent restenosis (ISR) in bare nitinol stents, with adjunctive Percutaneous Transluminal Angioplasty (PTA).

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Number	Device Name	Intended purpose per IFU
Class IIb		
60389	Philips Laser System	The Philips Laser System is used with Spectranetics Laser Catheters, each covered under their own Technical File or Dossier. The Instructions for Use for the Laser Catheters contain the Indications for each Laser Catheter that is powered by the Philips Laser System. The Indications for Use are also provided in the Technical File or Dossier for each of the Spectranetics Laser Catheters.

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1104	Turbo-Elite Laser Atherectomy Catheter	---
MD 0106	Lead Locking Device (LLD, LLD 1, LLD 2, LLD 3, LLD E, LLD EZ, LLD Accessory Kit, Lead Cutter)	---
MD 0106	Quick-Cross Capture Guidewire Retriever	---

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0106	TorqMax Sheath Grip Accessory	---

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List of Significant Subcontractors

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

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Subcontractor:	**Service(s) supplied**
MLase AG Industriestrasse 17 82110 Germering Germany	**Crucial Supplier**
Nordson MEDICAL Design and Development, Inc. 7125 Northland Terrace North Suite 200 Minneapolis Minnesota 55428 USA	**Manufacture**
Nordson MEDICAL Design and Development, Inc. 261 Cedar Hill Street Marlborough Massachusetts 01752 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Rose Medical 1440 Front Avenue NW Grand Rapids Michigan 49504 USA	**Crucial Supplier**
Spectranetics International B.V. Plesmanstraat 6 3833 LA Leusden The Netherlands	**EU Representative**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Synergy Health AST, LLC 3200 Lakeville Highway #120 Petaluma California 94954 USA	**Radiation (E Beam Sterilization)**
Synergy Health AST, LLC 9020 Activity Road, Suite D San Diego California 92126 USA	**Radiation (E Beam Sterilization)**
Terumo BCT Inc. 10811 W. Collins Avenue Lakewood Colorado 80215 USA	**ETO Sterilization**

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Date	Reference Number	Action
13 May 2009	7371731	First issue – Transfer from another Notified Body.
13 May 2009	7371732	Change of company name from Kensey Nash to Spectranetics.
03 December 2009	7461836	Extension to scope to add CVX-300 laser and laser catheters – transferred from another notified body. Addition of Sterigenics, Spectranetics, and Beam One to the list of significant subcontractors.
06 August 2010	7521078	"Scope clarified and expanded from: "The design and manufacture of Endovascular EmbolilThrombi Removal Devices, CVX·300 Laser and Laser Catheters"; to "The design and manufacture of Laser Medical Devices and their associated Endovascular Laser Atherectomy Catheters, Pacer Lead Removal Devices, and Defibrillator Lead Removal Devices; Aspiration Catheters for the removal of thrombus; Crossing / Support / Guiding Catheters for Coronary and/or Peripheral Use; and Accessories (Gauges, Coil Expanders, and Scissors)". Added BCT Caridian as a significant sterilization subcontractor. Also corrected various typographical errors in the name and addresses of significant subcontractors.
17 January 2011	10119550	Change of address from '96 Talamine Court, Colorado Springs, Colorado, 80907, USA' to '9965 Federal Drive, Colorado Springs, Colorado, 80921, USA' and addition of the word 'development' to the scope.

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Date	Reference Number	Action
09 February 2012	7779074	Renewal and scope clarified with sterility aspects of class I device Torqmax Sheath Accessory.
09 October 2013	8065822	Extension to scope and tech-file transfer (adding the Quick-Cross Guidewire Guiding Catheter-Retriever in which Spectranetics now becomes the legal manufacturer). Correction to scope (addition of "tubing set" accessories) which was discovered to have been inadvertently omitted during the original issue of the FQA certificate.
25 March 2014	8121394	Addition of Vention Medical Design and Development as a manufacturing significant subcontractor. Correction and update the name of an existing significant ETO sterilization subcontractor (from Caridian BCT Sterilization Services to TERUMO BCT). Clarification of the manufacturers existing FQA scope which now more explicitly describe the types of pacer and defribulator lead removal devices which are currently within in the manufacturers existing FQA scope.
07 May 2014	8121394	Removal of the manufacturers "Federal Drive" facility as a significant subcontractor - since that facility is listed as the legal manufacturer. Removal of sterilization activities from the manufacturers "Cascade" facility since sterilization no longer occurs there.

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Date	Reference Number	Action
23 September 2015	8419827	Remove Kensey Nash and Steris Isomedix from significant subcontractor list.
06 May 2016	8516129	Addition of Synergy Health AST, Lima, Ohio as significant subcontractor for E beam sterilization.
10 May 2016	8489478	Addition of Vention Medical Advanced Components (Minneapolis MN) as a significant subcontractor for Manufacture. Addition of Vascular occlusion catheters to device list.
22 February 2017	8664947	Renewal. Addition of Rose Medical for the service of "crucial supplier".
22 March 2018	8892055	Addition of Synergy Health (Steris) sites in Petaluma, California, USA and San Diego, California, USA as significant subcontractors for E Beam sterilization.
10 September 2018	8891243	Update name of Vention Medical Advanced Components (Minneapolis, Minnesota) to Nordson MEDICAL Advanced Components Inc. Update name of Vention Medical Design and Development, Inc. (Marlborough, Massachusetts) to Nordson MEDICAL Design and Development, Inc. (U.S.).
05 March 2019	7780642	Traceable to NB 0086.

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17 May 2019	9754463	Removal of Needle Holders from Scope. Removal of Synergy Health sites in Denver, Colorado and Lima, Ohio from list of significant subcontractors. Update name of Nordson MEDICAL Advanced Components, Inc. (Minneapolis, Minnesota) to Nordson MEDICAL Design and Development, Inc.
08 January 2020	3104089	Reduction of scope to remove "Aspiration Catheters for the removal of thrombus". Addition of products table in supplementary information section.
Current	3258097	Certificate Renewal. Removal of subcontractor Spectranetics (Cascade Ave., CO). Addition of subcontractor MLase AG (Germany). Update to product table to include Philips Laser System.