By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 632473**

Issued To: **Spectranetics Corporation**
5055 Brandin Court
Fremont
California
94538
USA

In respect of:

The Design, Development, and Manufacture of Sterile Dilation Catheters for Transluminal Angioplasty of Endovascular Stenotic Lesions.

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: **2015-09-11** Date: **2019-10-16** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 632473

Issued To:

Spectranetics Corporation
5055 Brandin Court
Fremont
California
94538
USA

Number	Device Name	Intended purpose per IFU
Class III		
---	AngioSculpt® PTCA Scoring Balloon Catheters	See CE 632474
Class IIa		
MD 0106	AngioSculpt® PTA Scoring Balloon Catheters	---

First Issued: **2015-09-11** Date: **2019-10-16** Expiry Date: **2024-05-26**

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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 632473**
Date:	**2019-10-16**
Issued To:	**Spectranetics Corporation** **5055 Brandin Court** **Fremont** **California** **94538** **USA**

Subcontractor:	**Service(s) supplied**
AdvancedCath 176 Component Drive San Jose California 95131 USA	**Manufacture**
Creganna Medical 1353 Dell Avenue Campbell California 95008 USA	**Manufacture**
Creganna Medical 8 Admiralty Street #07-10 Admirax 757438 Singapore	**Manufacture**

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

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Certificate No:	**CE 632473**
Date:	**2019-10-16**
Issued To:	**Spectranetics Corporation** **5055 Brandin Court** **Fremont** **California** **94538** **USA**

Subcontractor:	**Service(s) supplied**
Lumenous Device Technologies, Inc. 3030 Kenneth St. Santa Clara California 95054 USA	**Manufacture**
MeKo Laserstrahl-Materialbearbeitungen Im Kirchenfelde 12-14 Hannover D-31157 Sarstedt Germany	**Manufacture**
Spectranetics International B.V. Plesmanstraat 6 3833 LA Leusden The Netherlands	**EU Representative**

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

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	**ETO Sterilization**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 632473**

Date: **2019-10-16**

Issued To: **Spectranetics Corporation**
5055 Brandin Court
Fremont
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94538
USA

Date	Reference Number	Action
11 September 2015	8294940	First issue, transfer from another Notified Body.
07 June 2016	8500628	Certificate Renewal. Update subcontractor name Creganna Tactx Medical to Creganna Medical for both Campbell and Singapore subcontractor sites.
20 February 2019	9665745	Update address of subcontractor Lumenous Device Technologies, Inc. Remove Spectranetics Corporation (Colorado Springs) for Distribution.
21 February 2019	8917943	Traceable to NB 0086.
Current	9775920	Certificate Renewal. Added product table for existing devices.