

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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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.

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Supplementary Information to CE 632473

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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	---

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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.

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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
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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Subcontractor:	Service(s) supplied
Luminous 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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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**
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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 Luminous 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.

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