

EC Design-Examination Certificate

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

No. **CE 611679**
Issued To: **Spectranetics Corporation**
9965 Federal Drive
Colorado Springs
Colorado
80921
USA

In respect of:

TightRail, TightRail Mini, and TightRail Sub-C Rotating Mechanical Dilator Sheaths

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

First Issued: **2014-05-12**

Date: **2019-05-08**

Expiry Date: **2024-05-11**

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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 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.

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Supplementary Information to CE 611679

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Product:

TightRail, TightRail Mini, and TightRail Sub-C Rotating Mechanical Dilator Sheath Sets

Model Number	Device Name	Inner Diameter (F=French)	Working length (cm)	Intended Purpose per IFU	Classification
540-009	TightRail Mini Rotating Mechanical Dilator Sheath	9F	15.5 cm	The TightRail Rotating Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads.	Class III
540-011		11F	15.5 cm		Class III
545-509	TightRail Rotating Mechanical Dilator Sheath	9F	47.5 cm		Class III
545-511		11F	47.5 cm		Class III
545-513		13F	47.5 cm		Class III
560-009	TightRail Sub-C Rotating Mechanical Dilator Sheath	9F	15.5 cm		Class III
560-011		11F	15.5 cm		Class III
560-013		13F	15.5 cm		Class III

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Certificate History

Date	Reference Number	Action
12 May 2014	10145748	First Issue.
01 December 2014	10151989	Change of handle to "X-Drive" handle cam. Extension of shelf life to 2 years.
17 March 2016	10161253	Addition of TightRail Sub-C models 560-009, 560-011 and 560-013.
25 May 2016	10161936	Change to DuPont Tyvek 1073B packaging material – all product codes affected.
05 March 2019	7780642	Traceable to NB 0086.
Current	9690847	Certificate renewal. Remove "indwelling catheters and foreign objects" from intended purpose. Administrative update to product table.

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