

DECLARATION OF CONFORMITY

Manufacturer: Spectranetics Corporation
9965 Federal Drive
Colorado Springs, CO 80921
USA.

European Representative: Spectranetics International BV
Plesmanstraat 6
3833 LA Leusden, The Netherlands

Product Name	Model Number
TightRail™ Rotating Dilator Sheath	545-509, 545-511, 545-513
TightRail Mini™ Rotating Dilator Sheath	540-009, 540-011
TightRail™ Sub-C Rotating Dilator Sheath	560-009, 560-011, 560-013

GMDN: 38128 Vascular Dilator, Single Use

Certificates: ISO 13485 – Quality Management System – UKAS – MD 560307
ISO 13485 – Quality Management System – MDSAP 697018
Full Quality Assurance Anx II 3.2 BSI CE 550209
EC Design-Examination Certificate - CE 611679

Route to Conformity: Annex II, Full Quality Assurance

Classification: Class III, rule 6 according to Annex IX of the MDD

We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC for Medical Devices. The information contained within this Declaration of Conformity is issued under the responsibility of the Spectranetics Corporation.

Notified Body: BSI
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