

DECLARATION OF CONFORMITY

Legal Manufacturer: Spectranetics Corporation
5055 Brandin Court
Fremont, CA 94538
USA

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

Product: AngioSculpt[®] PTCA Scoring Balloon Catheter

Model Numbers: See attached product list

GMDN: 44088 Cutting / Scoring Coronary Angioplasty Balloon Catheter,
Single Use

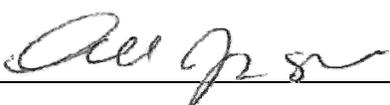
Certificates: ISO 13485 – Quality Management System – FM 632155
Full Quality Assurance Annex II excluding (4) - CE 632473
Design Examination - CE 632474

Classification: Class III, rule 7 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 and BSI International.

Notified Body: British Standards Institution
PO Box 6221
Kitemark Court
Davy Avenue
Milton Keynes
MK1 9EP
United Kingdom
Tel: +44 (0)8450 809000
Identification Number 0086

Signature, Date of Issue:

Name:	Amanda Johnson	
Title:	Vice President, Regulatory and Medical Affairs	
Signature:		Date: October 13, 2016

PRODUCT LIST	
AngioSculpt® PTCA Scoring Balloon Catheter	
Product Part Number	Product Description
PN-2001-2010	AngioSculpt Scoring Balloon Catheter, 2.0mm x 10mm
PN-2001-2015	AngioSculpt Scoring Balloon Catheter, 2.0mm x 15mm
PN-2001-2020	AngioSculpt Scoring Balloon Catheter, 2.0mm x 20mm
PN-2001-2510	AngioSculpt Scoring Balloon Catheter, 2.5mm x 10mm
PN-2001-2515	AngioSculpt Scoring Balloon Catheter, 2.5mm x 15mm
PN-2001-2520	AngioSculpt Scoring Balloon Catheter, 2.5mm x 20mm
PN-2001-3010	AngioSculpt Scoring Balloon Catheter, 3.0mm x 10mm
PN-2001-3015	AngioSculpt Scoring Balloon Catheter, 3.0mm x 15mm
PN-2001-3020	AngioSculpt Scoring Balloon Catheter, 3.0mm x 20mm
PN-2001-3510	AngioSculpt Scoring Balloon Catheter, 3.5mm x 10mm
PN-2001-3515	AngioSculpt Scoring Balloon Catheter, 3.5mm x 15mm
PN-2001-3520	AngioSculpt Scoring Balloon Catheter, 3.5mm x 20mm
PN-2043-2010	AngioSculpt Scoring Balloon Catheter, 2.0mm x 10mm, OTW EU
PN-2043-2015	AngioSculpt Scoring Balloon Catheter, 2.0mm x 15mm, OTW EU
PN-2043-2020	AngioSculpt Scoring Balloon Catheter, 2.0mm x 20mm, OTW EU
PN-2043-2510	AngioSculpt Scoring Balloon Catheter, 2.5mm x 10mm, OTW EU
PN-2043-2515	AngioSculpt Scoring Balloon Catheter, 2.5mm x 15mm, OTW EU
PN-2043-2520	AngioSculpt Scoring Balloon Catheter, 2.5mm x 20mm, OTW EU
PN-2043-3010	AngioSculpt Scoring Balloon Catheter, 3.0mm x 10mm, OTW EU
PN-2043-3015	AngioSculpt Scoring Balloon Catheter, 3.0mm x 15mm, OTW EU
PN-2043-3020	AngioSculpt Scoring Balloon Catheter, 3.0mm x 20mm, OTW EU
PN-2043-3510	AngioSculpt Scoring Balloon Catheter, 3.5mm x 10mm, OTW EU
PN-2043-3515	AngioSculpt Scoring Balloon Catheter, 3.5mm x 15mm, OTW EU
PN-2043-3520	AngioSculpt Scoring Balloon Catheter, 3.5mm x 20mm, OTW EU

PN-2200-2006	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.0mm x 6mm
PN-2200-2010	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.0mm x 10mm
PN-2200-2015	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.0mm x 15mm
PN-2200-2020	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.0mm x 20mm
PN-2200-2506	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.5mm x 6mm
PN-2200-2510	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.5mm x 10mm
PN-2200-2515	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.5mm x 15mm
PN-2200-2520	AngioSculpt PTCA Scoring Balloon Catheter, RX, 2.5mm x 20mm
PN-2200-3006	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.0mm x 6mm
PN-2200-3010	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.0mm x 10mm
PN-2200-3015	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.0mm x 15mm
PN-2200-3020	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.0mm x 20mm
PN-2200-3506	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.5mm x 6mm
PN-2200-3510	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.5mm x 10mm
PN-2200-3515	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.5mm x 15mm
PN-2200-3520	AngioSculpt PTCA Scoring Balloon Catheter, RX, 3.5mm x 20mm

REVISION HISTORY

Version (Rev)	Effective Date	CO #	Author	Change Description
A	6/2/2015	ECO020893	K. Kline	Initial release.
B	9/15/2015	ECO021878	K. Kline	Updated Certificate Numbers. Added SPNC to Part Numbers.
C	4/1/2016	ECO024151	K. Kline	Removed the SPNC suffix from Part Numbers.
D	10/28/2016	ECO026309	K. Kline	Reissued after approval of inner member tie layer material change (CE certificate re-issued).