



# Quality System Approval Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

**APPROVES THE QUALITY SYSTEM APPLIED BY**

## Penumbra, Inc.

**One Penumbra Place  
Alameda  
CA 94502  
USA**

*to the Product Family*

### **Intravascular Microflow Catheters (Penumbra Delivery MicroCatheters)**

**GMDN Code: 10691**

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex  
II, excluding (4)*

*The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

<b>Registration Number:</b>	<b>252.807</b>
<b>Original Approval:</b>	<b>30 June 2010</b>
<b>Last Amended on:</b>	<b>27 April 2016</b>
<b>Remains valid until:</b>	<b>29 June 2019</b>

**Signed:**

Approved by:  
Kevin D. Mullaney  
Chief Executive Officer - NSAI Inc.

Approved by:  
Susan Murphy  
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**  
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate  
**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**



# EC Design Examination Certificate

Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

**HAS EXAMINED THE DESIGN DOSSIER**  
Submitted by

## Penumbra, Inc.

**One Penumbra Place  
Alameda  
CA 94502  
USA**

*For Product Family*

**Intravascular Microflow Catheters  
(Penumbra Delivery MicroCatheters)**

**GMDN Code: 10691**

### CONCLUSION of EXAMINATION:

*NSAI have performed an examination of the design dossier relating to the above named product family and conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex (4)*

<b>Registration Number:</b>	<b>252.807</b>
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**Signed:**

Approved by:  
Kevin D. Mullaney  
Chief Executive Officer - NSAI Inc.

Approved by:  
Susan Murphy  
European Medical Device Operations Manager

### CONDITIONS OF VALIDITY:

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**

**Approved model numbers are included in the associated attachment**

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the product must receive further approval from NSAI.

**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**



# NSAI

## Attachment to Certificate 252.807 dated 30 June 2010

**This Certificate covers 36 model(s)**

Model Reference	Detail
PX400STR	PX 400™ Straight tip (150cm)
PX40045	PX 400™ 45° tip (150cm)
PX40090	PX 400™ 90° tip (150cm)
PX400J	PX 400™ 130° (J) tip (150cm)
PXSLIMSTR	PX SLIM™ 150 cm, Straight tip
PXSLIM045	PX SLIM™ 150 cm, 45° tip
PXSLIM090	PX SLIM™ 150 cm, 90° tip
PXSLIM130	PX SLIM™ 150 cm, 130° tip
PXSLIM160STR	PX SLIM™ 160 cm, Straight tip
PXSLIM160045	PX SLIM™ 160 cm, 45° tip
PXSLIM160090	PX SLIM™ 160 cm. 90° tip
PXSLIM160130	PX SLIM™ 160 cm, 130° tip
VEL150STR	Velocity® 150 cm, Straight tip
VEL150045	Velocity® 150 cm, 45° tip
VEL150090	Velocity® 150 cm, 90° tip
VEL150130	Velocity® 150 cm, 130° tip
VEL160STR	Velocity® 160 cm, Straight tip
VEL160045	Velocity® 160 cm, 45° tip
VEL160090	Velocity® 160 cm. 90° tip
VEL160130	Velocity® 160 cm, 130° tip
PXSLIMLAN115STR	LANTERN™ 115 cm, Straight tip
PXSLIMLAN115T45	LANTERN™ 115 cm, 45° tip
PXSLIMLAN115T90	LANTERN™ 115 cm, 90° tip
PXSLIMLAN115T130	LANTERN™ 115 cm, 130° tip



**Attachment to Certificate 252.807 dated 30 June 2010**

**This Certificate covers 36 model(s)**

Model Reference	Detail
PXSLIMLAN135STR	LANTERN™ 135 cm, Straight tip
PXSLIMLAN135T45	LANTERN™ 135 cm, 45° tip
PXSLIMLAN135T90	LANTERN™ 135 cm, 90° tip
PXSLIMLAN135T130	LANTERN™ 135 cm, 130° tip
PXSLIMLAN150STR	LANTERN™ 150 cm, Straight tip
PXSLIMLAN150T45	LANTERN™ 150 cm, 45° tip
PXSLIMLAN150T90	LANTERN™ 150 cm, 90° tip
PXSLIMLAN150T130	LANTERN™ 150 cm, 130° tip
PXSLIMLAN160STR	LANTERN™ 160 cm, Straight tip
PXSLIMLAN160T45	LANTERN™ 160 cm, 45° tip
PXSLIMLAN160T90	LANTERN™ 160 cm, 90° tip
PXSLIMLAN160T130	LANTERN™ 160 cm, 130° tip