

# NSAI

## 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.

1351 Harbor Bay Parkway  
Alameda  
CA 94502  
USA

*to the Product Family*

### Catheter, Embolectomy [INDIGO™ Aspiration System]

*on the basis of examination under the requirements of Annex II, Section 3 of Directive 93/42/EEC.  
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

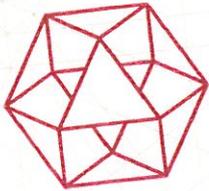
<b>Registration Number:</b>	<b>252.943</b>
<b>Original Approval:</b>	<b>18 September 2014</b>
<b>Last Amended on:</b>	<b>18 September 2014</b>
<b>Remains valid until:</b>	<b>17 September 2017</b>

**Signed:**

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

Approved by:  
Susan Murphy  
Risk Management Officer

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner .  
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI  
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**



**NSAI**

# 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.**

**1351 Harbor Bay Parkway  
Alameda  
CA 94502  
USA**

*For Product Family*

**Catheter, Embolectomy  
[INDIGO™ Aspiration System]**

## CONCLUSION of EXAMINATION:

Complies with the requirements of Annex II, Section 4 of Directive 93/42/EEC

<b>Registration Number:</b>	<b>252.943</b>
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**Signed:**

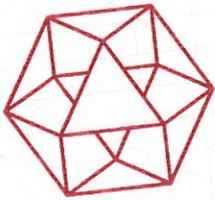
Approved by:  
Kevin D. Mullaney  
Chief Executive Officer - NSAI Inc.

Approved by:  
Susan Murphy  
Risk Management Officer

## CONDITIONS OF VALIDITY:

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**  
Note: 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 252.943 dated 18 September 2014

This Certificate covers 29 model(s)

Model Reference	Detail
CAT2	Aspiration Catheter 2
CAT3	Aspiration Catheter 3
CAT4	Aspiration Catheter 4
CAT5	Aspiration Catheter 5, 132cm
CAT5L125	Aspiration Catheter 5, 125cm
CAT5L127	Aspiration Catheter 5, 127cm
CAT5MP125	Aspiration Catheter 5, MP 125cm
CAT5MP127	Aspiration Catheter 5, MP 127cm
CAT3MAX	Aspiration Catheter 3MAX
CAT4MAX	Aspiration Catheter 4MAX, 139cm
CAT4MAX130	Aspiration Catheter 4MAX, 130cm
CAT4MAX125	Aspiration Catheter 4MAX, 125cm
CAT4MAXMP	Aspiration Catheter 4MAX, MP, 139cm
CAT4MAXMP130	Aspiration Catheter 4MAX, MP, 130cm
CAT4MAXMP125	Aspiration Catheter 4MAX, MP, 125cm
CAT5MAX	Aspiration Catheter 5MAX, 132cm
CAT5MAX125	Aspiration Catheter 5MAX, 125cm
CAT5MAX127	Aspiration Catheter 5MAX, 127cm
SEP2	Separator 2
SEP3	Separator 3
SEP3S	Separator 3S
SEP4	Separator 4
SEP5	Separator 5
FLEX2	Separator Flex 2
FLEX4	Separator Flex 4
FLEX5	Separator Flex 5
SEP3MAX	Separator 3MAX
IST1	Aspiration Tubing
IST2	Aspiration Tubing