



# 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.

**One Penumbra Place  
Alameda  
CA 94502  
USA**

*to the Product Family*

### Catheter, embolectomy (Penumbra System)

**GMDN Code: 58173 & 41978**

*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>252.711</b>
<b>Original Approval:</b>	<b>21 September 2006</b>
<b>Last Amended on:</b>	<b>22 September 2015</b>
<b>Remains valid until:</b>	<b>20 September 2018</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.**



# 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.

**One Penumbra Place**

**Alameda**

**CA 94502**

**USA**

*For Product Family*

**Catheter, embolectomy (Penumbra System).**

**GMDN Code: 58173 & 41978**

**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 Annex II, Section 4 of Directive 93/42/EEC

**Registration Number: 252.711**

**Original Approval: 21 September 2006**

**Last Amended on: 22 September 2015**

**Remains valid until: 20 September 2018**

**Signed:**

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

Approved by:  
Susan Murphy  
European Medical Device Operations Manager

#### CONDITIONS OF VALIDITY:

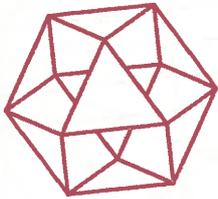
**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**

**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.**

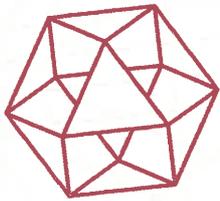


# NSAI

## Attachment to Certificate 252.711 dated 21 September 2006

**This Certificate covers 76 model(s)**

<u>Model Reference</u>	<u>Detail</u>
PSC054	Reperfusion Catheter 054 straight, 132
PSC054L127	Reperfusion Catheter 054 straight, 127
PSC054L125	Reperfusion Catheter 054 straight, 125
PSC054MP127	Reperfusion Catheter 054 MP shape, 127
PSC054MP125	Reperfusion Catheter 054 MP shape, 125
PSC041	Reperfusion Catheter 041
PSC032	Reperfusion Catheter 032
PSC026	Reperfusion Catheter 026
4 MAXC	Reperfusion Catheter 4MAX straight, 139
4MAXC130	Reperfusion Catheter 4MAX straight, 130
4 MAXC125	Reperfusion Catheter 4MAX straight, 125
4 MAXCMP	Reperfusion Catheter 4MAX straight, 139
4MAXCMP130	Reperfusion Catheter 4 MAX MP shape, 130
4MAXCMP125	Reperfusion Catheter 4MAX MP shape, 125
3MAXC	Reperfusion Catheter 3MAX
PSC054	Reperfusion Catheter 5MAX, 132
PSC054L127	Reperfusion Catheter 5MAX, 127
PSC054L125	Reperfusion Catheter 5MAX, 125
PSC054L115	Reperfusion Catheter 5MAX, 115
5MAXACE132	Reperfusion Catheter 5MAX ACE / ACE 60, 132
5MAXACE127	Reperfusion Catheter 5MAX ACE / ACE 60, 127
5MAXACE125	Reperfusion Catheter 5MAX ACE / ACE 60, 125
5MAXACE115	Reperfusion Catheter 5MAX ACE / ACE 60, 115
5MAXACE064L115	Reperfusion Catheter ACE 64, 115 cm

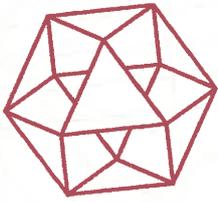


# NSAI

## Attachment to Certificate 252.711 dated 21 September 2006

This Certificate covers 76 model(s)

Model Reference	Detail
5MAXACE064L120	Reperfusion Catheter ACE 64, 120 cm
5MAXACE064L125	Reperfusion Catheter ACE 64, 125 cm
5MAXACE064L127	Reperfusion Catheter ACE 64, 127 cm
5MAXACE064	Reperfusion Catheter ACE 64, 132 cm
5MAXACE068L115	Reperfusion Catheter ACE 68, 115 cm
5MAXACE068L120	Reperfusion Catheter ACE 68, 120 cm
5MAXACE068L125	Reperfusion Catheter ACE 68, 125 cm
5MAXACE068L127	Reperfusion Catheter ACE 68, 127 cm
5MAXACE068	Reperfusion Catheter ACE 68, 132 cm
PSS054	Separator 054
PSS041	Separator 041
PSS032	Separator 032
PSS026	Separator 026
PSF054	Separator Flex 054 / 5MAX
PSF041	Separator Flex 041 / 4MAX
PSF032	Separator Flex 032
PSF026	Separator Flex 026
3MAXS	Separator 3MAX
PSS3D	Separator 3D
PSC054KIT	Reperfusion Catheter 054 straight, 132 – KIT
PSC054L127KIT	Reperfusion Catheter 054 straight, 127 - KIT
PSC054L125KIT	Reperfusion Catheter 054 straight, 125 - KIT
PSC054MP127KIT	Reperfusion Catheter 054 MP shape, 127 - KIT
PSC054MP125KIT	Reperfusion Catheter 054 MP shape, 125 - KIT

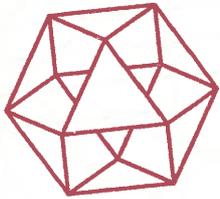


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## Attachment to Certificate 252.711 dated 21 September 2006

**This Certificate covers 76 model(s)**

<u>Model Reference</u>	<u>Detail</u>
PSC041KIT	Reperfusion Catheter 041 - KIT
PSC032KIT	Reperfusion Catheter 032 - KIT
PSC026KIT	Reperfusion Catheter 026 - KIT
4MAXCKIT	Reperfusion Catheter 4MAX straight, 139 - KIT
4MAXC130KIT	Reperfusion Catheter 4MAX straight, 130 - KIT
4MAXC125KIT	Reperfusion Catheter 4MAX straight, 125 - KIT
4MAXCMPKIT	Reperfusion Catheter 4MAX MP shape, 139 - KIT
4MAXCMP130KIT	Reperfusion Catheter 4MAX MP shape, 130 - KIT
4MAXCMP125KIT	Reperfusion Catheter 4MAX MP shape, 125 - KIT
3MAXCKIT	Reperfusion Catheter 3MAX - KIT
PSC054KIT	Reperfusion Catheter 5MAX, 132 - KIT
PSC054L127KIT	Reperfusion Catheter 5MAX, 127 - KIT
PSC054L125KIT	Reperfusion Catheter 5MAX, 125 - KIT
PSC054L115KIT	Reperfusion Catheter 5MAX, 115 - KIT
5MAXACE132KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 132 - KIT
5MAXACE127KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 127 - KIT
5MAXACE125KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 125 - KIT
5MAXACE115KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 115 - KIT
5MAXACE064KIT	Reperfusion Catheter ACE 64, 132 - KIT
5MAXACE064L127KIT	Reperfusion Catheter ACE 64, 127 - KIT
5MAXACE064L125KIT	Reperfusion Catheter ACE 64, 125 - KIT
5MAXACE064L120KIT	Reperfusion Catheter ACE 64, 120 - KIT
5MAXACE064L115KIT	Reperfusion Catheter ACE 64, 115 - KIT
5MAXACE068KIT	Reperfusion Catheter ACE 68, 132 - KIT



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## Attachment to Certificate 252.711 dated 21 September 2006

This Certificate covers 76 model(s)

<u>Model Reference</u>	<u>Detail</u>
5MAXACE068L127KIT	Reperfusion Catheter ACE 68, 127 - KIT
5MAXACE068L125KIT	Reperfusion Catheter ACE 68, 125 - KIT
5MAXACE068L120KIT	Reperfusion Catheter ACE 68, 120 - KIT
5MAXACE068L115KIT	Reperfusion Catheter ACE 68, 115 – KIT
<b>(Class IIa, Rule 2)</b>	
PST1	Aspiration Tubing
PST2	MAX Aspiration Tubing
PST3	Hi-Flow Aspiration Tubing