



# 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*

**Vascular guide-catheter, single-use  
(Neuron Intracranial Access System)**

**GMDN Code: 17846 & 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>252.761</b>
<b>Original Approval:</b>	<b>20 September 2007</b>
<b>Last Amended on:</b>	<b>18 March 2020</b>
<b>Remains valid until:</b>	<b>26 May 2024</b>

**Signed:**

Approved by:  
Dr. Caroline Dore Geraghty  
Director, Medical Devices

Approved by:  
Dr. Elaine Darcy  
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*

**Vascular guide-catheter, single-use  
(Neuron Intracranial Access System)**

**GMDN Code: 17846 & 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 II (4)*

<b>Registration Number:</b>	<b>252.761</b>
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**Signed:**

Approved by:  
Dr. Caroline Dore Geraghty  
Director, Medical Devices

Approved by:  
Dr. Elaine Darcy  
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.**

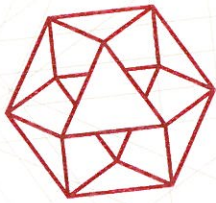


## Attachment to Certificate 252.761 dated 20 September 2007

### This Certificate covers 50 model(s)

Model Reference	Detail
PND6F11512	Neuron Delivery Catheter (115cm/12cm)
PND6F11512M	Neuron Delivery Catheter (115cm/12cm - MP)
PND6F1156	Neuron Delivery Catheter (115cm/6cm)
PND6F1156M	Neuron Delivery Catheter (115cm/6cm - MP)
PND6F10512	Neuron Delivery Catheter (105cm/12cm)
PND6F10512M	Neuron Delivery Catheter (105cm/12cm - MP)
PND6F1056	Neuron Delivery Catheter (105cm/6cm)
PND6F1056M	Neuron Delivery Catheter (105cm/6cm - MP)
PND6F070956	Neuron Delivery Catheter (95cm/6cm)
PND6F070956M	Neuron Delivery Catheter (95cm/6cm – MP)
PND6F0701058	Neuron Delivery Catheter (105cm/8cm)
PND6F0701058M	Neuron Delivery Catheter (105cm/8cm –MP)
PNS5F130SIM	Neuron Select Catheter 130 (Simmons)
PNS5F130H1	Neuron Select Catheter 130 (H1)
PNS5F130BER	Neuron Select Catheter 130 (BER)
PNS5F120SIM	Neuron Select Catheter 120 (Simmons)
PNS5F120H1	Neuron Select Catheter 120 (H1)
PNS5F120BER	Neuron Select Catheter 120 (Berenstein)
PNML6F088704M	6F 088 Neuron MAX Long Sheath 70/4 MP
PNML6F088704	6F 088 Neuron MAX Long Sheath 70/4 Straight
PNML6F088804M	6F 088 Neuron MAX Long Sheath 80/4 MP
PNML6F088804	6F 088 Neuron MAX Long Sheath 80/4 Straight
PNML6F088904M	6F 088 Neuron MAX Long Sheath 90/4 MP
PNML6F088904	6F 088 Neuron MAX Long Sheath 90/4 Straight
PNML6F0881004M	6F 088 Neuron MAX Long Sheath 100/4 MP
PNML6F0881004	6F 088 Neuron MAX Long Sheath 100/4 Straight
PNML6F088704MR	6F 088 Neuron MAX Long Sheath 70/4 MP RHV
PNML6F088704R	6F 088 Neuron MAX Long Sheath 70/4 Straight RHV
PNML6F088804MR	6F 088 Neuron MAX Long Sheath 80/4 MP RHV
PNML6F088804R	6F 088 Neuron MAX Long Sheath 80/4 Straight RHV





# NSAI

## Attachment to Certificate 252.761 dated 20 September 2007

**This Certificate covers 50 model(s)**

Model Reference	Detail
PNML6F088904MR	6F 088 Neuron MAX Long Sheath 90/4 MP RHV
PNML6F088904R	6F 088 Neuron MAX Long Sheath 90/4 Straight RHV
PNML6F0881004MR	6F 088 Neuron MAX Long Sheath 100/4 MP RHV
PNML6F0881004R	6F 088 Neuron MAX Long Sheath 100/4 Straight RHV
PNMD8F088704M	8F 088 Neuron MAX 088 Delivery Catheter 70/4 MP
PNMD8F088704	8F 088 Neuron MAX 088 Delivery Catheter 70/4 Straight
PNMD8F088804M	8F 088 Neuron MAX 088 Delivery Catheter 80/4 MP
PNMD8F088804	8F 088 Neuron MAX 088 Delivery Catheter 80/4 Straight
PNMD8F088904M	8F 088 Neuron MAX 088 Delivery Catheter 90/4 MP
PNMD8F088904	8F 088 Neuron MAX 088 Delivery Catheter 90/4 Straight
PNMD8F0881004M	8F 088 Neuron MAX 088 Delivery Catheter 100/4 MP
PNMD8F0881004	8F 088 Neuron MAX 088 Delivery Catheter 100/4 Straight
PNS6F125SIM	6F Neuron Select Catheter 125 SIM
PNS6F125H1	6F Neuron Select Catheter 125 H1
PNS6F125BER	6F Neuron Select Catheter 125 BER
PNS6F125SIMV	6F Neuron Select Catheter 125 SIM-V
PNS6F105SIM	6F Neuron Select Catheter 105 SIM
PNS6F105H1	6F Neuron Select Catheter 105 H1
PNS6F105BER	6F Neuron Select Catheter 105 BER
PNS6F105SIMV	6F Neuron Select Catheter 105 SIM-V