



# 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*

**Vascular guide-catheter, single use  
(Benchmark™ 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>252.932</b>
<b>Original Approval:</b>	<b>15 July 2014</b>
<b>Last Amended on:</b>	<b>1 April 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.**



# 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*

**Vascular guide-catheter, single use  
(Benchmark™ 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>252.932</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:

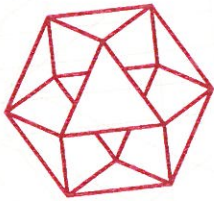
**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**

**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.**



# NSAI

## Attachment to Certificate 252.932 dated 15 July 2014

This Certificate covers 30 model(s)

Model Reference	Detail
BMK6F95	6F Benchmark 95cm Straight
BMK6F95M	6F Benchmark 95cm MP
BMK6F105	6F Benchmark 105cm Straight
BMK6F105M	6F Benchmark 105cm MP
BMK6F115	6F Benchmark 115cm Straight
BMK6F115M	6F Benchmark 115cm MP
BMK6F95BER120	6F Benchmark 95cm Straight + 5F BER 120cm Select
BMK6F95H1120	6F Benchmark 95cm Straight + 5F H1 120cm Select
BMK6F95SIM120	6F Benchmark 95cm Straight + 5F SIM 120cm Select
BMK6F95BER130	6F Benchmark 95cm Straight + 5F BER 130cm Select
BMK6F95H1130	6F Benchmark 95cm Straight + 5F H1 130cm Select
BMK6F95SIM130	6F Benchmark 95cm Straight + 5F SIM 130cm Select
BMK6F95MBER120	6F Benchmark 95cm MP + 5F BER 120cm Select
BMK6F95MH1120	6F Benchmark 95cm MP + 5F H1 120cm Select
BMK6F95MSIM120	6F Benchmark 95cm MP + 5F SIM 120cm Select
BMK6F95MBER130	6F Benchmark 95cm MP + 5F BER 130cm Select
BMK6F95MH1130	6F Benchmark 95cm MP + 5F H1 130cm Select
BMK6F95MSIM130	6F Benchmark 95cm MP + 5F SIM 130cm Select
BMK6F105BER130	6F Benchmark 105cm Straight + 5F BER 130cm Select
BMK6F105H1130	6F Benchmark 105cm Straight + 5F H1 130cm Select
BMK6F105SIM130	6F Benchmark 105cm Straight + 5F SIM 130cm Select
BMK6F105MBER130	6F Benchmark 105cm MP + 5F BER 130cm Select
BMK6F105MH1130	6F Benchmark 105cm MP + 5F H1 130cm Select
BMK6F105MSIM130	6F Benchmark 105cm MP + 5F SIM 130cm Select
PNS5F130H1	5F Select Catheter (130cm - H1)
PNS5F130SIM	5F Select Catheter (130cm - Simmons)
PNS5F130BER	5F Select Catheter (130cm - BER)
PNS5F120H1	5F Select Catheter (120cm - H1)
PNS5F120SIM	5F Select Catheter (120cm - Simmons)
PNS5F120BER	5F Select Catheter (120cm - BER)