



# 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*

### Embolization Implant Kit (POD® System)

**GMDN Code: 43980**

#### 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>252.934</b>
<b>Original Approval:</b>	<b>15 July 2014</b>
<b>Last Amended on:</b>	<b>12 September 2017</b>
<b>Remains valid until:</b>	<b>14 July 2020</b>

**Signed:**

Approved by:  
Geraldine Larkin  
Chief Executive Officer, NSAI

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

## 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*

### Embolization Implant Kit (POD® System)

**GMDN Code: 43980**

*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.*

**Registration Number: 252.934**

**Original Approval: 15 July 2014**

**Last Amended on: 12 September 2017**

**Remains valid until: 14 July 2020**

**Signed:**

Approved by:  
Geraldine Larkin  
Chief Executive Officer, NSAI

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

## Attachment to Certificate 252.934 dated 15 July 2014

### This Certificate covers 292 model(s)

Catalog Number	Description	Catalog Number	Description
POD Short			
RBYP0D4S	POD Short, 4mm x 20cm	RBYP0D6S	POD Short, 6mm x 35cm
RBYP0D5S	POD Short, 5mm x 20cm	RBYP0D8S	POD Short, 8mm x 40cm
POD			
RBYP0D420	POD, 4mm x 20cm	RBYP0D645	POD, 6mm x 45cm
RBYP0D425	POD, 4mm x 25cm	RBYP0D6	POD, 6mm x 50cm
RBYP0D4	POD, 4mm x 30cm	RBYP0D655	POD, 6mm x 55cm
RBYP0D435	POD, 4mm x 35cm	RBYP0D660	POD, 6mm x 60cm
RBYP0D440	POD, 4mm x 40cm	RBYP0D6H30	POD, 6.5mm x 30cm
RBYP0D4H20	POD, 4.5mm x 20cm	RBYP0D6H35	POD, 6.5mm x 35cm
RBYP0D4H25	POD, 4.5mm x 25cm	RBYP0D6H40	POD, 6.5mm x 40cm
RBYP0D4H30	POD, 4.5mm x 30cm	RBYP0D6H45	POD, 6.5mm x 45cm
RBYP0D4H35	POD, 4.5mm x 35cm	RBYP0D6H50	POD, 6.5mm x 50cm
RBYP0D4H40	POD, 4.5mm x 40cm	RBYP0D6H55	POD, 6.5mm x 55cm
RBYP0D520	POD, 5mm x 20cm	RBYP0D6H60	POD, 6.5mm x 60cm
RBYP0D525	POD, 5mm x 25cm	RBYP0D730	POD, 7mm x 30cm
RBYP0D5	POD, 5mm x 30cm	RBYP0D735	POD, 7mm x 35cm
RBYP0D535	POD, 5mm x 35cm	RBYP0D740	POD, 7mm x 40cm
RBYP0D540	POD, 5mm x 40cm	RBYP0D745	POD, 7mm x 45cm
RBYP0D545	POD, 5mm x 45cm	RBYP0D750	POD, 7mm x 50cm
RBYP0D550	POD, 5mm x 50cm	RBYP0D755	POD, 7mm x 55cm
RBYP0D555	POD, 5mm x 55cm	RBYP0D760	POD, 7mm x 60cm
RBYP0D560	POD, 5mm x 60cm	RBYP0D7H30	POD, 7.5mm x 30cm
RBYP0D5H20	POD, 5.5mm x 20cm	RBYP0D7H35	POD, 7.5mm x 35cm
RBYP0D5H25	POD, 5.5mm x 25cm	RBYP0D7H40	POD, 7.5mm x 40cm
RBYP0D5H30	POD, 5.5mm x 30cm	RBYP0D7H45	POD, 7.5mm x 45cm
RBYP0D5H35	POD, 5.5mm x 35cm	RBYP0D7H50	POD, 7.5mm x 50cm
RBYP0D5H40	POD, 5.5mm x 40cm	RBYP0D7H55	POD, 7.5mm x 55cm
RBYP0D5H45	POD, 5.5mm x 45cm	RBYP0D7H60	POD, 7.5mm x 60cm
RBYP0D5H50	POD, 5.5mm x 50cm	RBYP0D840	POD, 8mm x 40cm
RBYP0D5H55	POD, 5.5mm x 55cm	RBYP0D845	POD, 8mm x 45cm
RBYP0D5H60	POD, 5.5mm x 60cm	RBYP0D850	POD, 8mm x 50cm



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RBYP0D630	POD, 6mm x 30cm	RBYP0D855	POD, 8mm x 55cm
RBYP0D635	POD, 6mm x 35cm	RBYP0D8	POD, 8mm x 60cm
RBYP0D640	POD, 6mm x 40cm		

#### POD Long

RBYP0D4L20	POD Long, 4mm x 20cm	RBYP0D6L45	POD Long, 6mm x 45cm
RBYP0D4L25	POD Long, 4mm x 25cm	RBYP0D6L50	POD Long, 6mm x 50cm
RBYP0D4L30	POD Long, 4mm x 30cm	RBYP0D6L55	POD Long, 6mm x 55cm
RBYP0D4L	POD Long, 4mm x 35cm	RBYP0D6L60	POD Long, 6mm x 60cm
RBYP0D4L40	POD Long, 4mm x 40cm	RBYP0D6HL30	POD Long, 6.5mm x 30cm
RBYP0D4HL20	POD Long, 4.5mm x 20cm	RBYP0D6HL35	POD Long, 6.5mm x 35cm
RBYP0D4HL25	POD Long, 4.5mm x 25cm	RBYP0D6HL40	POD Long, 6.5mm x 40cm
RBYP0D4HL30	POD Long, 4.5mm x 30cm	RBYP0D6HL45	POD Long, 6.5mm x 45cm
RBYP0D4HL35	POD Long, 4.5mm x 35cm	RBYP0D6HL50	POD Long, 6.5mm x 50cm
RBYP0D4HL40	POD Long, 4.5mm x 40cm	RBYP0D6HL55	POD Long, 6.5mm x 55cm
RBYP0D5L20	POD Long, 5mm x 20cm	RBYP0D6HL60	POD Long, 6.5mm x 60cm
RBYP0D5L25	POD Long, 5mm x 25cm	RBYP0D7L30	POD Long, 7mm x 30cm
RBYP0D5L30	POD Long, 5mm x 30cm	RBYP0D7L35	POD Long, 7mm x 35cm
RBYP0D5L35	POD Long, 5mm x 35cm	RBYP0D7L40	POD Long, 7mm x 40cm
RBYP0D5L	POD Long, 5mm x 40cm	RBYP0D7L45	POD Long, 7mm x 45cm
RBYP0D5L45	POD Long, 5mm x 45cm	RBYP0D7L50	POD Long, 7mm x 50cm
RBYP0D5L50	POD Long, 5mm x 50cm	RBYP0D7L55	POD Long, 7mm x 55cm
RBYP0D5L55	POD Long, 5mm x 55cm	RBYP0D7L60	POD Long, 7mm x 60cm
RBYP0D5L60	POD Long, 5mm x 60cm	RBYP0D7HL30	POD Long, 7.5mm x 30cm
RBYP0D5HL20	POD Long, 5.5mm x 20cm	RBYP0D7HL35	POD Long, 7.5mm x 35cm
RBYP0D5HL25	POD Long, 5.5mm x 25cm	RBYP0D7HL40	POD Long, 7.5mm x 40cm
RBYP0D5HL30	POD Long, 5.5mm x 30cm	RBYP0D7HL45	POD Long, 7.5mm x 45cm
RBYP0D5HL35	POD Long, 5.5mm x 35cm	RBYP0D7HL50	POD Long, 7.5mm x 50cm
RBYP0D5HL40	POD Long, 5.5mm x 40cm	RBYP0D7HL55	POD Long, 7.5mm x 55cm
RBYP0D5HL45	POD Long, 5.5mm x 45cm	RBYP0D7HL60	POD Long, 7.5mm x 60cm
RBYP0D5HL50	POD Long, 5.5mm x 50cm	RBYP0D8L40	POD Long, 8mm x 40cm
RBYP0D5HL55	POD Long, 5.5mm x 55cm	RBYP0D8L45	POD Long, 8mm x 45cm
RBYP0D5HL60	POD Long, 5.5mm x 60cm	RBYP0D8L50	POD Long, 8mm x 50cm
RBYP0D6L30	POD Long, 6mm x 30cm	RBYP0D8L55	POD Long, 8mm x 55cm
RBYP0D6L35	POD Long, 6mm x 35cm	RBYP0D8L60	POD Long, 8mm x 60cm



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RBYP0D6L40      POD Long, 6mm x 40cm

#### POD Packing Coil J Soft

RBYP0DJ1	POD Packing Coil 1 cm	RBYP0DJ15	POD Packing Coil 15 cm
RBYP0DJ2	POD Packing Coil 2 cm	RBYP0DJ20	POD Packing Coil 20 cm
RBYP0DJ3	POD Packing Coil 3 cm	RBYP0DJ25	POD Packing Coil 25 cm
RBYP0DJ4	POD Packing Coil 4 cm	RBYP0DJ30	POD Packing Coil 30 cm
RBYP0DJ5	POD Packing Coil 5 cm	RBYP0DJ35	POD Packing Coil 35 cm
RBYP0DJ6	POD Packing Coil 6 cm	RBYP0DJ40	POD Packing Coil 40 cm
RBYP0DJ7	POD Packing Coil 7 cm	RBYP0DJ45	POD Packing Coil 45 cm
RBYP0DJ8	POD Packing Coil 8 cm	RBYP0DJ50	POD Packing Coil 50 cm
RBYP0DJ9	POD Packing Coil 9 cm	RBYP0DJ55	POD Packing Coil 55 cm
RBYP0DJ10	POD Packing Coil 10 cm	RBYP0DJ60	POD Packing Coil 60 cm

#### POD Short (Neuro)

400POD4S	POD Short, 4mm x 20cm	400POD6S	POD Short, 6mm x 35cm
400POD5S	POD Short, 5mm x 20cm	400POD8S	POD Short, 8mm x 40cm

#### POD (Neuro)

400POD420	POD, 4mm x 20cm	400POD645	POD, 6mm x 45cm
400POD425	POD, 4mm x 25cm	400POD6	POD, 6mm x 50cm
400POD4	POD, 4mm x 30cm	400POD655	POD, 6mm x 55cm
400POD435	POD, 4mm x 35cm	400POD660	POD, 6mm x 60cm
400POD440	POD, 4mm x 40cm	400POD6H30	POD, 6.5mm x 30cm
400POD4H20	POD, 4.5mm x 20cm	400POD6H35	POD, 6.5mm x 35cm
400POD4H25	POD, 4.5mm x 25cm	400POD6H40	POD, 6.5mm x 40cm
400POD4H30	POD, 4.5mm x 30cm	400POD6H45	POD, 6.5mm x 45cm
400POD4H35	POD, 4.5mm x 35cm	400POD6H50	POD, 6.5mm x 50cm
400POD4H40	POD, 4.5mm x 40cm	400POD6H55	POD, 6.5mm x 55cm
400POD520	POD, 5mm x 20cm	400POD6H60	POD, 6.5mm x 60cm
400POD525	POD, 5mm x 25cm	400POD730	POD, 7mm x 30cm
400POD5	POD, 5mm x 30cm	400POD735	POD, 7mm x 35cm
400POD535	POD, 5mm x 35cm	400POD740	POD, 7mm x 40cm
400POD540	POD, 5mm x 40cm	400POD745	POD, 7mm x 45cm



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400POD545	POD, 5mm x 45cm	400POD750	POD, 7mm x 50cm
400POD550	POD, 5mm x 50cm	400POD755	POD, 7mm x 55cm
400POD555	POD, 5mm x 55cm	400POD760	POD, 7mm x 60cm
400POD560	POD, 5mm x 60cm	400POD7H30	POD, 7.5mm x 30cm
400POD5H20	POD, 5.5mm x 20cm	400POD7H35	POD, 7.5mm x 35cm
400POD5H25	POD, 5.5mm x 25cm	400POD7H40	POD, 7.5mm x 40cm
400POD5H30	POD, 5.5mm x 30cm	400POD7H45	POD, 7.5mm x 45cm
400POD5H35	POD, 5.5mm x 35cm	400POD7H50	POD, 7.5mm x 50cm
400POD5H40	POD, 5.5mm x 40cm	400POD7H55	POD, 7.5mm x 55cm
400POD5H45	POD, 5.5mm x 45cm	400POD7H60	POD, 7.5mm x 60cm
400POD5H50	POD, 5.5mm x 50cm	400POD840	POD, 8mm x 40cm
400POD5H55	POD, 5.5mm x 55cm	400POD845	POD, 8mm x 45cm
400POD5H60	POD, 5.5mm x 60cm	400POD850	POD, 8mm x 50cm
400POD630	POD, 6mm x 30cm	400POD855	POD, 8mm x 55cm
400POD635	POD, 6mm x 35cm	400POD8	POD, 8mm x 60cm
400POD640	POD, 6mm x 40cm		

#### POD Long (Neuro)

400POD4L20	POD Long, 4mm x 20cm	400POD6L45	POD Long, 6mm x 45cm
400POD4L25	POD Long, 4mm x 25cm	400POD6L50	POD Long, 6mm x 50cm
400POD4L30	POD Long, 4mm x 30cm	400POD6L55	POD Long, 6mm x 55cm
400POD4L	POD Long, 4mm x 35cm	400POD6L60	POD Long, 6mm x 60cm
400POD4L40	POD Long, 4mm x 40cm	400POD6HL30	POD Long, 6.5mm x 30cm
400POD4HL20	POD Long, 4.5mm x 20cm	400POD6HL35	POD Long, 6.5mm x 35cm
400POD4HL25	POD Long, 4.5mm x 25cm	400POD6HL40	POD Long, 6.5mm x 40cm
400POD4HL30	POD Long, 4.5mm x 30cm	400POD6HL45	POD Long, 6.5mm x 45cm
400POD4HL35	POD Long, 4.5mm x 35cm	400POD6HL50	POD Long, 6.5mm x 50cm
400POD4HL40	POD Long, 4.5mm x 40cm	400POD6HL55	POD Long, 6.5mm x 55cm
400POD5L20	POD Long, 5mm x 20cm	400POD6HL60	POD Long, 6.5mm x 60cm
400POD5L25	POD Long, 5mm x 25cm	400POD7L30	POD Long, 7mm x 30cm
400POD5L30	POD Long, 5mm x 30cm	400POD7L35	POD Long, 7mm x 35cm
400POD5L35	POD Long, 5mm x 35cm	400POD7L40	POD Long, 7mm x 40cm
400POD5L	POD Long, 5mm x 40cm	400POD7L45	POD Long, 7mm x 45cm
400POD5L45	POD Long, 5mm x 45cm	400POD7L50	POD Long, 7mm x 50cm
400POD5L50	POD Long, 5mm x 50cm	400POD7L55	POD Long, 7mm x 55cm



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400POD5L55	POD Long, 5mm x 55cm	400POD7L60	POD Long, 7mm x 60cm
400POD5L60	POD Long, 5mm x 60cm	400POD7HL30	POD Long, 7.5mm x 30cm
400POD5HL20	POD Long, 5.5mm x 20cm	400POD7HL35	POD Long, 7.5mm x 35cm
400POD5HL25	POD Long, 5.5mm x 25cm	400POD7HL40	POD Long, 7.5mm x 40cm
400POD5HL30	POD Long, 5.5mm x 30cm	400POD7HL45	POD Long, 7.5mm x 45cm
400POD5HL35	POD Long, 5.5mm x 35cm	400POD7HL50	POD Long, 7.5mm x 50cm
400POD5HL40	POD Long, 5.5mm x 40cm	400POD7HL55	POD Long, 7.5mm x 55cm
400POD5HL45	POD Long, 5.5mm x 45cm	400POD7HL60	POD Long, 7.5mm x 60cm
400POD5HL50	POD Long, 5.5mm x 50cm	400POD8L40	POD Long, 8mm x 40cm
400POD5HL55	POD Long, 5.5mm x 55cm	400POD8L45	POD Long, 8mm x 45cm
400POD5HL60	POD Long, 5.5mm x 60cm	400POD8L50	POD Long, 8mm x 50cm
400POD6L30	POD Long, 6mm x 30cm	400POD8L55	POD Long, 8mm x 55cm
400POD6L35	POD Long, 6mm x 35cm	400POD8L60	POD Long, 8mm x 60cm
400POD6L40	POD Long, 6mm x 40cm		

#### POD Packing Coil J Soft (Neuro)

400PODJ1	POD Packing Coil 1 cm	400PODJ15	POD Packing Coil 15 cm
400PODJ2	POD Packing Coil 2 cm	400PODJ20	POD Packing Coil 20 cm
400PODJ3	POD Packing Coil 3 cm	400PODJ25	POD Packing Coil 25 cm
400PODJ4	POD Packing Coil 4 cm	400PODJ30	POD Packing Coil 30 cm
400PODJ5	POD Packing Coil 5 cm	400PODJ35	POD Packing Coil 35 cm
400PODJ6	POD Packing Coil 6 cm	400PODJ40	POD Packing Coil 40 cm
400PODJ7	POD Packing Coil 7 cm	400PODJ45	POD Packing Coil 45 cm
400PODJ8	POD Packing Coil 8 cm	400PODJ50	POD Packing Coil 50 cm
400PODJ9	POD Packing Coil 9 cm	400PODJ55	POD Packing Coil 55 cm
400PODJ10	POD Packing Coil 10 cm	400PODJ60	POD Packing Coil 60 cm