



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Penumbra, Inc.**  
**One Penumbra Place**  
**Alameda, CA 94502**  
**USA**

has been assessed and deemed to comply with the requirements  
of the above standard in respect of the scope of operations given  
below:

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**The Design, Manufacture and Distribution of Medical Devices for the  
Treatment of Neuro, Peripheral and Cardiovascular Disease  
Including: Delivery Catheters, Aspiration Catheters, Separators,  
Revascularization Devices, Embolization Implants, and Neurosurgical  
Aspiration Devices. The Design, Manufacture, Distribution, and  
Service of Active Aspiration Systems. The Distribution of  
Neurosurgical and Intravascular Access and Treatment Devices.**

**Additional sites covered under this multi-site certification are listed on the Annex  
(File No. MD19.4277)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

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Registration Number: MD19.4277  
Certification Granted: August 21, 2007  
Effective Date: August 28, 2021  
Expiry Date: August 27, 2024





## **Annex to Certificate Number: MD19.4277**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.**

### **Activity**

### **Location**

Administration, Design,  
Manufacturing, Distribution

Penumbra, Inc.  
One Penumbra Place  
Building 1351  
Alameda, CA 94502  
USA  
File No.: MD19.4277

Administration, Design,  
Manufacturing, Distribution

Penumbra, Inc.  
One Penumbra Place  
Building 1321  
Alameda, CA 94502  
USA  
File No.: MD19.4277/A

Design

Penumbra, Inc.  
One Penumbra Place  
Building 1411  
Alameda, CA 94502  
USA  
File No.: MD19.4277/B

Distribution

Penumbra Europe GmbH  
Am Borsigturm 44  
13507 Berlin  
Germany  
File No.: MD19.4277/C



## **Annex to Certificate Number: MD19.4277**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.**

#### **Activity**

#### **Location**

Distribution

Penumbra, Inc.  
6336 Patterson Pass Rd  
Suite D  
Livermore, CA 94550  
USA  
File No.: MD19.4277/D

Manufacturing

Penumbra, Inc.  
One Penumbra Place  
Building 1301  
Alameda, CA 94502  
USA  
File No.: MD19.4277/E

Distribution

Penumbra, Inc.  
6262 Patterson Pass Rd  
Suite A  
Livermore, CA 94550  
USA  
File No.: MD19.4277/F

Manufacturing

Penumbra, Inc.  
One Penumbra Place  
Building 1401  
Alameda, CA 94502  
USA  
File No.: MD19.4277/G



## **Annex to Certificate Number: MD19.4277**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.**

### **Activity**

### **Location**

Distribution

Penumbra Neuro Australia Pty  
Suite 3, Level 5, 1 Oxford St  
Darlinghurst  
Sydney NSW  
Australia  
File No.: MD19.4277/H

Distribution

Crossmed SpA,  
Via Giuseppe di Vittorio 2/C  
10098 Rivoli Torino  
Italy  
File No.: MD19.4277/I

Distribution

Crossmed SpA,  
Via Primaticcio 184,  
2017 Milano  
Italy  
File No.: MD19.4277/J

Distribution

Penumbra, Inc.  
1070 South 3800 West  
Suite 500  
Salt Lake City, UT 84104  
USA  
File No.: MD19.4277/K



# NSAI

**Annex to Certificate Number: MD19.4277**

## **Scope of Registration:**

**The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.**

### **Activity**

Manufacturing

### **Location**

Penumbra, Inc.  
630 Roseville Parkway  
Roseville, CA 95747  
USA  
File No.: MD19.4277/L

**Verified by:  
Operations Manager**

## Declaration of Conformity

Manufacturer: Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502, USA

Authorized EC Representative: Penumbra Europe GmbH  
Am Borsigturm 44  
13507 Berlin, Germany

Design / Manufacturing Facility: Penumbra, Inc.  
One Penumbra Place  
Alameda, CA 94502, USA

Product Category: Catheter, Embolectomy  
Product Trade Name: INDIGO™ Aspiration System  
Products: See Attachment(s)

Classification: Aspiration Catheter & Separator:  
Class III based on Annex IX, Rule 6 of Directive 93/42/EEC, as amended.  
Aspiration Tubing:  
Class IIa based on Annex IX, Rule 2 of Directive 93/42/EEC, as amended.

GMDN Code: Aspiration Catheter & Separator:  
58173 - Thrombectomy suction catheter  
Aspiration Tubing:  
41978 - Surgical irrigation/aspiration system

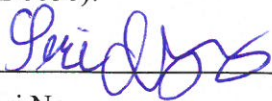
Selected conformity assessment procedure Directive 93/42/EEC Annex II

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), as amended, including 2007/47/EC which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by:

- The Penumbra, Inc. Quality System Certificate based on I.S. EN ISO 13485: 2016 (MD19.4277, expiration date 27 August 2021), issued by NSAI (Dublin, Ireland).
- The MDD Quality System Certificate, Annex II.3 of the EC Directive (252.943, expiration date 17 September 2022), issued by NSAI (Dublin, Ireland, CE 0050).
- The Penumbra, Inc. EC Design Examination Certificate in accordance with Annex II.4 of the EC-Directive (252.943, expiration date 17 September 2022), issued by NSAI (Dublin, Ireland, CE 0050).

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

03 Mar 2020

Name &

Teri Nguyen

Title:

Regulatory Affairs Specialist II

## ATTACHMENT TO THE DECLARATION OF CONFORMITY

### Product List: "INDIGO™ System" (Class III, Rule 6)

Catalog No.	Device Name
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
CAT6STR30	Aspiration Catheter 6, Straight, 30cm
CAT6STR40	Aspiration Catheter 6, Straight, 40cm
CAT6STR50	Aspiration Catheter 6, Straight, 50cm
CAT6STR60	Aspiration Catheter 6, Straight, 60cm
CAT6STR70	Aspiration Catheter 6, Straight, 70cm
CAT6STR80	Aspiration Catheter 6, Straight, 80cm
CAT6STR90	Aspiration Catheter 6, Straight, 90cm
CAT6STR100	Aspiration Catheter 6, Straight, 100cm
CAT6STR110	Aspiration Catheter 6, Straight, 110cm
CAT6STR115	Aspiration Catheter 6, Straight, 115cm
CAT6STR120	Aspiration Catheter 6, Straight, 120cm
CAT6STR125	Aspiration Catheter 6, Straight, 125cm
CAT6STR132	Aspiration Catheter 6, Straight, 132cm
CAT6	Aspiration Catheter 6, Straight, 135cm
CAT6MP30	Aspiration Catheter 6, MP, 30cm
CAT6MP40	Aspiration Catheter 6, MP, 40cm
CAT6MP50	Aspiration Catheter 6, MP, 50cm
CAT6MP60	Aspiration Catheter 6, MP, 60cm
CAT6MP70	Aspiration Catheter 6, MP, 70cm
CAT6MP80	Aspiration Catheter 6, MP, 80cm
CAT6MP90	Aspiration Catheter 6, MP, 90cm
CAT6MP100	Aspiration Catheter 6, MP, 100cm
CAT6MP110	Aspiration Catheter 6, MP, 110cm
CAT6MP115	Aspiration Catheter 6, MP, 115cm
CAT6MP120	Aspiration Catheter 6, MP, 120cm
CAT6MP125	Aspiration Catheter 6, MP, 125cm
CAT6MP132	Aspiration Catheter 6, MP, 132cm
CAT6MP135	Aspiration Catheter 6, MP, 135cm

## ATTACHMENT TO THE DECLARATION OF CONFORMITY

CAT8STR30	Aspiration Catheter 8, Straight, 30cm
CAT8STR40	Aspiration Catheter 8, Straight, 40cm
CAT8STR50	Aspiration Catheter 8, Straight, 50cm
CAT8STR60	Aspiration Catheter 8, Straight, 60cm
CAT8STR70	Aspiration Catheter 8, Straight, 70cm
CAT8STR80	Aspiration Catheter 8, Straight, 80cm
CAT8STR85	Aspiration Catheter 8, Straight, 85cm
CAT8STR90	Aspiration Catheter 8, Straight, 90cm
CAT8STR95	Aspiration Catheter 8, Straight, 95cm
CAT8STR100	Aspiration Catheter 8, Straight, 100cm
CAT8STR110	Aspiration Catheter 8, Straight, 110cm
CAT8STR115	Aspiration Catheter 8, Straight, 115cm
CAT8TORQ30	Aspiration Catheter 8, TORQ, 30cm
CAT8TORQ40	Aspiration Catheter 8, TORQ, 40cm
CAT8TORQ50	Aspiration Catheter 8, TORQ, 50cm
CAT8TORQ60	Aspiration Catheter 8, TORQ, 60cm
CAT8TORQ70	Aspiration Catheter 8, TORQ, 70cm
CAT8TORQ80	Aspiration Catheter 8, TORQ, 80cm
CAT8TORQ85	Aspiration Catheter 8, TORQ, 85cm
CAT8TORQ95	Aspiration Catheter 8, TORQ, 95cm
CAT8TORQ110	Aspiration Catheter 8, TORQ, 110cm
CAT8XTORQ90	Aspiration Catheter 8, XTORQ, 90cm
CAT8XTORQ100	Aspiration Catheter 8, XTORQ, 100cm
CAT8XTORQ115	Aspiration Catheter 8, XTORQ, 115cm
INHLSTR30	INHALE, Straight, 30cm
INHLSTR40	INHALE, Straight, 40cm
INHLSTR50	INHALE, Straight, 50cm
INHLSTR60	INHALE, Straight, 60cm
INHLSTR70	INHALE, Straight, 70cm
INHLSTR80	INHALE, Straight, 80cm
INHLSTR85	INHALE, Straight, 85cm
INHLSTR90	INHALE, Straight, 90cm
INHLSTR100	INHALE, Straight, 100cm
INHLSTR110	INHALE, Straight, 110cm
INHLSTR115	INHALE, Straight, 115cm
INHL30	INHALE, MP, 30cm
INHL40	INHALE, MP, 40cm
INHL50	INHALE, MP, 50cm
INHL60	INHALE, MP, 60cm
INHL70	INHALE, MP, 70cm
INHL80	INHALE, MP, 80cm
INHL85	INHALE, MP, 85cm
INHL90	INHALE, MP, 90cm
INHL100	INHALE, MP, 100cm
INHL110	INHALE, MP, 110cm
INHL115	INHALE, MP, 115cm
SEP2	Separator 2
SEP3	Separator 3
SEP3S	Separator 3S

## ATTACHMENT TO THE DECLARATION OF CONFORMITY

SEP4	Separator 4
SEP5	Separator 5
FLEX2	Separator Flex 2
FLEX4	Separator Flex 4
FLEX5	Separator Flex 5
SEP3MAX	Separator 3MAX
SEP6	Separator 6
SEP8	Separator 8, 150cm
SEPD	Separator 8, 90cm
CATD30	Aspiration Catheter D, MP, 30cm - KIT
CATD35	Aspiration Catheter D, MP, 35cm - KIT
CATD40	Aspiration Catheter D, MP, 40cm - KIT
CATD45	Aspiration Catheter D, MP, 45cm - KIT
CATD	Aspiration Catheter D, MP, 50cm - KIT
CATD30STR	Aspiration Catheter D, Straight, 30cm - KIT
CATD35STR	Aspiration Catheter D, Straight, 35cm - KIT
CATD40STR	Aspiration Catheter D, Straight, 40cm - KIT
CATD45STR	Aspiration Catheter D, Straight, 45cm - KIT
CATD50STR	Aspiration Catheter D, Straight, 50cm - KIT
CAT2KIT	Aspiration Catheter 2 - KIT
CAT3KIT	Aspiration Catheter 3 - KIT
CAT4KIT	Aspiration Catheter 4 - KIT
CAT5KIT	Aspiration Catheter 5, 132cm - KIT
CAT5L125KIT	Aspiration Catheter 5, 125cm - KIT
CAT5L127KIT	Aspiration Catheter 5, 127cm - KIT
CAT5MP125KIT	Aspiration Catheter 5, MP 125cm - KIT
CAT5MP127KIT	Aspiration Catheter 5, MP 127cm - KIT
CAT3MAXKIT	Aspiration Catheter 3MAX - KIT
CAT4MAXKIT	Aspiration Catheter 4MAX, 139cm - KIT
CAT4MAX130KIT	Aspiration Catheter 4MAX, 130cm - KIT
CAT4MAX125KIT	Aspiration Catheter 4MAX, 125cm - KIT
CAT4MAXMPKIT	Aspiration Catheter 4MAX, MP, 139cm - KIT
CAT4MAXMP130KIT	Aspiration Catheter 4MAX, MP, 130cm - KIT
CAT4MAXMP125KIT	Aspiration Catheter 4MAX, MP, 125cm - KIT
CAT5MAXKIT	Aspiration Catheter 5MAX, 132cm - KIT
CAT5MAX125KIT	Aspiration Catheter 5MAX, 125cm - KIT
CAT5MAX127KIT	Aspiration Catheter 5MAX, 127cm - KIT
CAT6STR30KIT	Aspiration Catheter 6, Straight, 30cm - KIT
CAT6STR40KIT	Aspiration Catheter 6, Straight, 40cm - KIT
CAT6STR50KIT	Aspiration Catheter 6, Straight, 50cm - KIT
CAT6STR60KIT	Aspiration Catheter 6, Straight, 60cm - KIT
CAT6STR70KIT	Aspiration Catheter 6, Straight, 70cm - KIT
CAT6STR80KIT	Aspiration Catheter 6, Straight, 80cm - KIT
CAT6STR90KIT	Aspiration Catheter 6, Straight, 90cm - KIT
CAT6STR100KIT	Aspiration Catheter 6, Straight, 100cm - KIT
CAT6STR110KIT	Aspiration Catheter 6, Straight, 110cm - KIT
CAT6STR115KIT	Aspiration Catheter 6, Straight, 115cm - KIT
CAT6STR120KIT	Aspiration Catheter 6, Straight, 120cm - KIT
CAT6STR125KIT	Aspiration Catheter 6, Straight, 125cm - KIT

## ATTACHMENT TO THE DECLARATION OF CONFORMITY

CAT6STR132KIT	Aspiration Catheter 6, Straight, 132cm - KIT
CAT6KIT	Aspiration Catheter 6, Straight, 135cm - KIT
CAT6MP30KIT	Aspiration Catheter 6, MP, 30cm - KIT
CAT6MP40KIT	Aspiration Catheter 6, MP, 40cm - KIT
CAT6MP50KIT	Aspiration Catheter 6, MP, 50cm - KIT
CAT6MP60KIT	Aspiration Catheter 6, MP, 60cm - KIT
CAT6MP70KIT	Aspiration Catheter 6, MP, 70cm - KIT
CAT6MP80KIT	Aspiration Catheter 6, MP, 80cm - KIT
CAT6MP90KIT	Aspiration Catheter 6, MP, 90cm - KIT
CAT6MP100KIT	Aspiration Catheter 6, MP, 100cm - KIT
CAT6MP110KIT	Aspiration Catheter 6, MP, 110cm - KIT
CAT6MP115KIT	Aspiration Catheter 6, MP, 115cm - KIT
CAT6MP120KIT	Aspiration Catheter 6, MP, 120cm - KIT
CAT6MP125KIT	Aspiration Catheter 6, MP, 125cm - KIT
CAT6MP132KIT	Aspiration Catheter 6, MP, 132cm - KIT
CAT6MP135KIT	Aspiration Catheter 6, MP, 135cm - KIT
CAT8STR30KIT	Aspiration Catheter 8, Straight, 30cm - KIT
CAT8STR40KIT	Aspiration Catheter 8, Straight, 40cm - KIT
CAT8STR50KIT	Aspiration Catheter 8, Straight, 50cm - KIT
CAT8STR60KIT	Aspiration Catheter 8, Straight, 60cm - KIT
CAT8STR70KIT	Aspiration Catheter 8, Straight, 70cm - KIT
CAT8STR80KIT	Aspiration Catheter 8, Straight, 80cm - KIT
CAT8STR85KIT	Aspiration Catheter 8, Straight, 85cm - KIT
CAT8STR90KIT	Aspiration Catheter 8, Straight, 90cm - KIT
CAT8STR95KIT	Aspiration Catheter 8, Straight, 95cm - KIT
CAT8STR100KIT	Aspiration Catheter 8, Straight, 100cm - KIT
CAT8STR110KIT	Aspiration Catheter 8, Straight, 110cm - KIT
CAT8STR115KIT	Aspiration Catheter 8, Straight, 115cm - KIT
CAT8TORQ30KIT	Aspiration Catheter 8, TORQ, 30cm - KIT
CAT8TORQ40KIT	Aspiration Catheter 8, TORQ, 40cm - KIT
CAT8TORQ50KIT	Aspiration Catheter 8, TORQ, 50cm - KIT
CAT8TORQ60KIT	Aspiration Catheter 8, TORQ, 60cm - KIT
CAT8TORQ70KIT	Aspiration Catheter 8, TORQ, 70cm - KIT
CAT8TORQ80KIT	Aspiration Catheter 8, TORQ, 80cm - KIT
CAT8TORQ85KIT	Aspiration Catheter 8, TORQ, 85cm - KIT
CAT8TORQ95KIT	Aspiration Catheter 8, TORQ, 95cm - KIT
CAT8TORQ110KIT	Aspiration Catheter 8, TORQ, 110cm - KIT
CAT8XTORQ90KIT	Aspiration Catheter 8, XTORQ, 90cm - KIT
CAT8XTORQ100KIT	Aspiration Catheter 8, XTORQ, 100cm - KIT
CAT8XTORQ115KIT	Aspiration Catheter 8, XTORQ, 115cm - KIT
<b>(Class IIa, Rule 2)</b>	
IST1	Aspiration Tubing
IST2	Aspiration Tubing
IST3	Aspiration Tubing
IST4	Aspiration Tubing

End of Product List



# 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*

### **Thrombectomy Suction Catheter [INDIGO™ Aspiration System]**

**GMDN Code: 58173 & 41978**

*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: 252.943**

**Original Approval: 18 September 2014**

**Last Amended on: 20 November 2018**

**Remains valid until: 17 September 2022**

**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.**



# 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*

**Thrombectomy Suction Catheter [INDIGO™ Aspiration 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 Directive 93/42/EEC on Medical Devices, Annex II (4)*

**Registration Number: 252.943**

**Original Approval: 18 September 2014**

**Last Amended on: 20 November 2018**

**Remains valid until: 17 September 2022**

**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.**



## Attachment to Certificate 252.943 dated 18 September 2014

**This Certificate covers 188 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
CAT6STR30	Aspiration Catheter 6, Straight, 30cm
CAT6STR40	Aspiration Catheter 6, Straight, 40cm
CAT6STR50	Aspiration Catheter 6, Straight, 50cm
CAT6STR60	Aspiration Catheter 6, Straight, 60cm
CAT6STR70	Aspiration Catheter 6, Straight, 70cm
CAT6STR80	Aspiration Catheter 6, Straight, 80cm
CAT6STR90	Aspiration Catheter 6, Straight, 90cm
CAT6STR100	Aspiration Catheter 6, Straight, 100cm
CAT6STR110	Aspiration Catheter 6, Straight, 110cm
CAT6STR115	Aspiration Catheter 6, Straight, 115cm
CAT6STR120	Aspiration Catheter 6, Straight, 120cm
CAT6STR125	Aspiration Catheter 6, Straight, 125cm
CAT6STR132	Aspiration Catheter 6, Straight, 132cm
CAT6	Aspiration Catheter 6, Straight, 135cm
CAT6MP30	Aspiration Catheter 6, MP, 30cm
CAT6MP40	Aspiration Catheter 6, MP, 40cm
CAT6MP50	Aspiration Catheter 6, MP, 50cm
CAT6MP60	Aspiration Catheter 6, MP, 60cm
CAT6MP70	Aspiration Catheter 6, MP, 70cm



## Attachment to Certificate 252.943 dated 18 September 2014

**This Certificate covers 188 model(s)**

Model Reference	Detail
CAT6MP80	Aspiration Catheter 6, MP, 80cm
CAT6MP90	Aspiration Catheter 6, MP, 90cm
CAT6MP100	Aspiration Catheter 6, MP, 100cm
CAT6MP110	Aspiration Catheter 6, MP, 110cm
CAT6MP115	Aspiration Catheter 6, MP, 115cm
CAT6MP120	Aspiration Catheter 6, MP, 120cm
CAT6MP125	Aspiration Catheter 6, MP, 125cm
CAT6MP132	Aspiration Catheter 6, MP, 132cm
CAT6MP135	Aspiration Catheter 6, MP, 135cm
CAT8STR30	Aspiration Catheter 8, Straight, 30cm
CAT8STR40	Aspiration Catheter 8, Straight, 40cm
CAT8STR50	Aspiration Catheter 8, Straight, 50cm
CAT8STR60	Aspiration Catheter 8, Straight, 60cm
CAT8STR70	Aspiration Catheter 8, Straight, 70cm
CAT8STR80	Aspiration Catheter 8, Straight, 80cm
CAT8STR85	Aspiration Catheter 8, Straight, 85cm
CAT8STR90	Aspiration Catheter 8, Straight, 90cm
CAT8STR95	Aspiration Catheter 8, Straight, 95cm
CAT8STR100	Aspiration Catheter 8, Straight, 100cm
CAT8STR110	Aspiration Catheter 8, Straight, 110cm
CAT8STR115	Aspiration Catheter 8, Straight, 115cm
CAT8TORQ30	Aspiration Catheter 8, TORQ, 30cm
CAT8TORQ40	Aspiration Catheter 8, TORQ, 40cm
CAT8TORQ50	Aspiration Catheter 8, TORQ, 50cm
CAT8TORQ60	Aspiration Catheter 8, TORQ, 60cm
CAT8TORQ70	Aspiration Catheter 8, TORQ, 70cm
CAT8TORQ80	Aspiration Catheter 8, TORQ, 80cm
CAT8TORQ85	Aspiration Catheter 8, TORQ, 85cm
CAT8TORQ95	Aspiration Catheter 8, TORQ, 95cm
CAT8TORQ110	Aspiration Catheter 8, TORQ, 110cm
CAT8XTORQ90	Aspiration Catheter 8, XTORQ, 90cm
CAT8XTORQ100	Aspiration Catheter 8, XTORQ, 100cm
CAT8XTORQ115	Aspiration Catheter 8, XTORQ, 115cm
INHLSTR30	INHALE, Straight, 30cm
INHLSTR40	INHALE, Straight, 40cm
INHLSTR50	INHALE, Straight, 50cm
INHLSTR60	INHALE, Straight, 60cm



## Attachment to Certificate 252.943 dated 18 September 2014

**This Certificate covers 188 model(s)**

Model Reference	Detail
INHLSTR70	INHALE, Straight, 70cm
INHLSTR80	INHALE, Straight, 80cm
INHLSTR85	INHALE, Straight, 85cm
INHLSTR90	INHALE, Straight, 90cm
INHLSTR100	INHALE, Straight, 100cm
INHLSTR110	INHALE, Straight, 110cm
INHLSTR115	INHALE, Straight, 115cm
INHL30	INHALE, MP, 30cm
INHL40	INHALE, MP, 40cm
INHL50	INHALE, MP, 50cm
INHL60	INHALE, MP, 60cm
INHL70	INHALE, MP, 70cm
INHL80	INHALE, MP, 80cm
INHL85	INHALE, MP, 85cm
INHL90	INHALE, MP, 90cm
INHL100	INHALE, MP, 100cm
INHL110	INHALE, MP, 110cm
INHL115	INHALE, MP, 115cm
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
SEP6	Separator 6
SEP8	Separator 8, 150cm
SEPD	Separator 8, 90cm
CATD30	Aspiration Catheter D, MP, 30cm - KIT
CATD35	Aspiration Catheter D, MP, 35cm - KIT
CATD40	Aspiration Catheter D, MP, 40cm - KIT
CATD45	Aspiration Catheter D, MP, 45cm - KIT
CATD	Aspiration Catheter D, MP, 50cm - KIT
CATD30STR	Aspiration Catheter D, Straight, 30cm - KIT
CATD35STR	Aspiration Catheter D, Straight, 35cm - KIT



## Attachment to Certificate 252.943 dated 18 September 2014

**This Certificate covers 188 model(s)**

Model Reference	Detail
CATD40STR	Aspiration Catheter D, Straight, 40cm - KIT
CATD45STR	Aspiration Catheter D, Straight, 45cm - KIT
CATD50STR	Aspiration Catheter D, Straight, 50cm - KIT
CAT2KIT	Aspiration Catheter 2 - KIT
CAT3KIT	Aspiration Catheter 3 - KIT
CAT4KIT	Aspiration Catheter 4 - KIT
CAT5KIT	Aspiration Catheter 5, 132cm - KIT
CAT5L125KIT	Aspiration Catheter 5, 125cm - KIT
CAT5L127KIT	Aspiration Catheter 5, 127cm - KIT
CAT5MP125KIT	Aspiration Catheter 5, MP 125cm - KIT
CAT5MP127KIT	Aspiration Catheter 5, MP 127cm - KIT
CAT3MAXKIT	Aspiration Catheter 3MAX - KIT
CAT4MAXKIT	Aspiration Catheter 4MAX, 139cm - KIT
CAT4MAX130KIT	Aspiration Catheter 4MAX, 130cm - KIT
CAT4MAX125KIT	Aspiration Catheter 4MAX, 125cm - KIT
CAT4MAXMPKIT	Aspiration Catheter 4MAX, MP, 139cm - KIT
CAT4MAXMP130KIT	Aspiration Catheter 4MAX, MP, 130cm - KIT
CAT4MAXMP125KIT	Aspiration Catheter 4MAX, MP, 125cm - KIT
CAT5MAXKIT	Aspiration Catheter 5MAX, 132cm - KIT
CAT5MAX125KIT	Aspiration Catheter 5MAX, 125cm - KIT
CAT5MAX127KIT	Aspiration Catheter 5MAX, 127cm - KIT
CAT6STR30KIT	Aspiration Catheter 6, Straight, 30cm - KIT
CAT6STR40KIT	Aspiration Catheter 6, Straight, 40cm - KIT
CAT6STR50KIT	Aspiration Catheter 6, Straight, 50cm - KIT
CAT6STR60KIT	Aspiration Catheter 6, Straight, 60cm - KIT
CAT6STR70KIT	Aspiration Catheter 6, Straight, 70cm - KIT
CAT6STR80KIT	Aspiration Catheter 6, Straight, 80cm - KIT
CAT6STR90KIT	Aspiration Catheter 6, Straight, 90cm - KIT
CAT6STR100KIT	Aspiration Catheter 6, Straight, 100cm - KIT
CAT6STR110KIT	Aspiration Catheter 6, Straight, 110cm - KIT
CAT6STR115KIT	Aspiration Catheter 6, Straight, 115cm - KIT
CAT6STR120KIT	Aspiration Catheter 6, Straight, 120cm - KIT
CAT6STR125KIT	Aspiration Catheter 6, Straight, 125cm - KIT
CAT6STR132KIT	Aspiration Catheter 6, Straight, 132cm - KIT
CAT6KIT	Aspiration Catheter 6, Straight, 135cm - KIT
CAT6MP30KIT	Aspiration Catheter 6, MP, 30cm - KIT
CAT6MP40KIT	Aspiration Catheter 6, MP, 40cm - KIT



## Attachment to Certificate 252.943 dated 18 September 2014

**This Certificate covers 188 model(s)**

Model Reference	Detail
CAT6MP50KIT	Aspiration Catheter 6, MP, 50cm - KIT
CAT6MP60KIT	Aspiration Catheter 6, MP, 60cm - KIT
CAT6MP70KIT	Aspiration Catheter 6, MP, 70cm - KIT
CAT6MP80KIT	Aspiration Catheter 6, MP, 80cm - KIT
CAT6MP90KIT	Aspiration Catheter 6, MP, 90cm - KIT
CAT6MP100KIT	Aspiration Catheter 6, MP, 100cm - KIT
CAT6MP110KIT	Aspiration Catheter 6, MP, 110cm - KIT
CAT6MP115KIT	Aspiration Catheter 6, MP, 115cm - KIT
CAT6MP120KIT	Aspiration Catheter 6, MP, 120cm - KIT
CAT6MP125KIT	Aspiration Catheter 6, MP, 125cm - KIT
CAT6MP132KIT	Aspiration Catheter 6, MP, 132cm - KIT
CAT6MP135KIT	Aspiration Catheter 6, MP, 135cm - KIT
CAT8STR30KIT	Aspiration Catheter 8, Straight, 30cm - KIT
CAT8STR40KIT	Aspiration Catheter 8, Straight, 40cm - KIT
CAT8STR50KIT	Aspiration Catheter 8, Straight, 50cm - KIT
CAT8STR60KIT	Aspiration Catheter 8, Straight, 60cm - KIT
CAT8STR70KIT	Aspiration Catheter 8, Straight, 70cm - KIT
CAT8STR80KIT	Aspiration Catheter 8, Straight, 80cm - KIT
CAT8STR85KIT	Aspiration Catheter 8, Straight, 85cm - KIT
CAT8STR90KIT	Aspiration Catheter 8, Straight, 90cm - KIT
CAT8STR95KIT	Aspiration Catheter 8, Straight, 95cm - KIT
CAT8STR100KIT	Aspiration Catheter 8, Straight, 100cm - KIT
CAT8STR110KIT	Aspiration Catheter 8, Straight, 110cm - KIT
CAT8STR115KIT	Aspiration Catheter 8, Straight, 115cm - KIT
CAT8TORQ30KIT	Aspiration Catheter 8, TORQ, 30cm - KIT
CAT8TORQ40KIT	Aspiration Catheter 8, TORQ, 40cm - KIT
CAT8TORQ50KIT	Aspiration Catheter 8, TORQ, 50cm - KIT
CAT8TORQ60KIT	Aspiration Catheter 8, TORQ, 60cm - KIT
CAT8TORQ70KIT	Aspiration Catheter 8, TORQ, 70cm - KIT
CAT8TORQ80KIT	Aspiration Catheter 8, TORQ, 80cm - KIT
CAT8TORQ85KIT	Aspiration Catheter 8, TORQ, 85cm - KIT
CAT8TORQ95KIT	Aspiration Catheter 8, TORQ, 95cm - KIT
CAT8TORQ110KIT	Aspiration Catheter 8, TORQ, 110cm - KIT
CAT8XTORQ90KIT	Aspiration Catheter 8, XTORQ, 90cm - KIT
CAT8XTORQ100KIT	Aspiration Catheter 8, XTORQ, 100cm - KIT
CAT8XTORQ115KIT	Aspiration Catheter 8, XTORQ, 115cm - KIT



**Attachment to Certificate 252.943 dated 18 September 2014**

**This Certificate covers 188 model(s)**

**Model Reference**

**Detail**

	<b>(Class IIa, Rule 2)</b>
IST1	Aspiration Tubing
IST2	Aspiration Tubing
IST3	Aspiration Tubing
IST4	Aspiration Tubing