



# 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



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### **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



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### **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



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## **Activity**

Manufacturing

## **Location**

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

**Verified by:  
Operations Manager**