



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:

The Design, Manufacture, and Distribution of Medical Devices for the Treatment of Neuro, Peripheral, and Cardio Vascular 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

Registration Number: MD19.4277
Certification Granted: August 21, 2007
Effective Date: November 13, 2019
Expiry Date: August 27, 2021



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800



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 Cardio Vascular 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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Annex to Certificate Number: MD19.4277

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Activity

Location

Distribution

Crossmed SpA,
Via Giuseppe di Vittorio 2/C
10098 Rivoli Torino
Italy
File No.: MP19.4277/I

Distribution

Crossmed SpA,
Via Primaticcio 184,
2017 Milano
Italy
File No.: MP19.4277/J

Distribution

Penumbra, Inc.
1070 South 3800 West
Suite 500
Salt Lake City, UT 84104
USA
File No.: MP19.4277/K

**Verified by:
Operations Manager**