



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:

Vascular guide-catheter, single use

Product Trade Name:

Neuron™ Intracranial Access System

Products:

See Attachment(s)

Classification:

Class III based on Annex IX, Rule 6 of Directive 93/42/EEC, as amended.

GMDN Code:

Delivery Catheter:

17846 - Vascular guide-catheter, single use

Select Catheter:

10691 - Intravascular microflow catheter

Selected conformity assessment procedure:

Annex II of Directive 93/42/EEC, as amended

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 (252.761, expiration date 26 May 2024), issued by NSAI (Dublin, Ireland, CE 0050).
- The Penumbra, Inc. EC Design Examination Certificate in accordance with Annex II.4 of the EC-Directive (252.761, expiration date 26 May 2024), issued by NSAI (Dublin, Ireland, CE 0050).

Signature:

 Date: 01 Apr 2020

Name &
Title:

Michaela Mahl
Senior Manager of Regulatory Affairs

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Product List: "Neuron™ Intracranial Access System" (Class III, Rule 6)

Catalog Number	Device Name
PND6F11512	Neuron Delivery Catheter (115cm/12cm)
PND6F11512M	Neuron Delivery Catheter (115cm/12cm - MP)
PND6F1156	Neuron Delivery Catheter (115cm/6cm)
PND6F1156M	Neuron Delivery Catheter (115cm/6cm - MP)
PND6F10512	Neuron Delivery Catheter (105cm/12cm)
PND6F10512M	Neuron Delivery Catheter (105cm/12cm - MP)
PND6F1056	Neuron Delivery Catheter (105cm/6cm)
PND6F1056M	Neuron Delivery Catheter (105cm/6cm - MP)
PND6F070956	Neuron Delivery Catheter (95cm/6cm)
PND6F070956M	Neuron Delivery Catheter (95cm/6cm - MP)
PND6F0701058	Neuron Delivery Catheter (105cm/8cm)
PND6F0701058M	Neuron Delivery Catheter (105cm/8cm - MP)
PNS5F130H1	Neuron Select Catheter 130 (H1)
PNS5F130SIM	Neuron Select Catheter 130 (Simmons)
PNS5F130BER	Neuron Select Catheter 130 (BER)
PNS5F120H1	Neuron Select Catheter 120 (H1)
PNS5F120SIM	Neuron Select Catheter 120 (Simmons)
PNS5F120BER	Neuron Select Catheter 120 (BER)
PNML6F088704M	6F 088 Neuron MAX Long Sheath 70/4 MP
PNML6F088704	6F 088 Neuron MAX Long Sheath 70/4 Straight
PNML6F088804M	6F 088 Neuron MAX Long Sheath 80/4 MP
PNML6F088804	6F 088 Neuron MAX Long Sheath 80/4 Straight
PNML6F088904M	6F 088 Neuron MAX Long Sheath 90/4 MP
PNML6F088904	6F 088 Neuron MAX Long Sheath 90/4 Straight
PNML6F0881004M	6F 088 Neuron MAX Long Sheath 100/4 MP
PNML6F0881004	6F 088 Neuron MAX Long Sheath 100/4 Straight
PNML6F088704MR	6F 088 Neuron MAX Long Sheath 70/4 MP RHV
PNML6F088704R	6F 088 Neuron MAX Long Sheath 70/4 Straight RHV
PNML6F088804MR	6F 088 Neuron MAX Long Sheath 80/4 MP RHV
PNML6F088804R	6F 088 Neuron MAX Long Sheath 80/4 Straight RHV
PNML6F088904MR	6F 088 Neuron MAX Long Sheath 90/4 MP RHV
PNML6F088904R	6F 088 Neuron MAX Long Sheath 90/4 Straight RHV
PNML6F0881004MR	6F 088 Neuron MAX Long Sheath 100/4 MP RHV
PNML6F0881004R	6F 088 Neuron MAX Long Sheath 100/4 Straight RHV
PNMD8F088704M	8F 088 Neuron MAX 088 Delivery Catheter 70/4 MP
PNMD8F088704	8F 088 Neuron MAX 088 Delivery Catheter 70/4 Straight
PNMD8F088804M	8F 088 Neuron MAX 088 Delivery Catheter 80/4 MP
PNMD8F088804	8F 088 Neuron MAX 088 Delivery Catheter 80/4 Straight
PNMD8F088904M	8F 088 Neuron MAX 088 Delivery Catheter 90/4 MP
PNMD8F088904	8F 088 Neuron MAX 088 Delivery Catheter 90/4 Straight

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Catalog Number	Device Name
PNMD8F0881004M	8F 088 Neuron MAX 088 Delivery Catheter 100/4 MP
PNMD8F0881004	8F 088 Neuron MAX 088 Delivery Catheter 100/4 Straight
PNS6F125SIM	6F Neuron Select Catheter 125 SIM
PNS6F125H1	6F Neuron Select Catheter 125 H1
PNS6F125BER	6F Neuron Select Catheter 125 BER
PNS6F125SIMV	6F Neuron Select Catheter 125 SIM-V
PNS6F105SIM	6F Neuron Select Catheter 105 SIM
PNS6F105H1	6F Neuron Select Catheter 105 H1
PNS6F105BER	6F Neuron Select Catheter 105 BER
PNS6F105SIMV	6F Neuron Select Catheter 105 SIM-V

End of Product List



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 and development, manufacture, and distribution of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including, delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

The manufacture and distribution of subassemblies and components for delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, and neurosurgical aspiration devices.

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)**

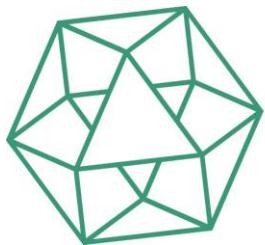
Approved by:

Kevin Mullaney

Director of Certification

Registration Number: MD19.4277
Certification Granted: August 21, 2007
Effective Date: August 28, 2024
Expiry Date: August 27, 2027





NSAI

Annex to Certificate Number: MD19.4277

Facility Locations, Scope and Activities

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

Scope:

The manufacture of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

The manufacture of subassemblies and components for delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, and neurosurgical aspiration devices.

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

Scope:

The manufacture of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

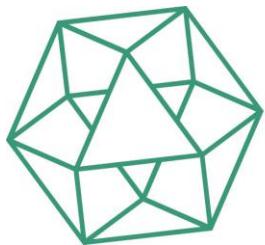
The manufacture of subassemblies and components for delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, and neurosurgical aspiration devices.

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

Scope:

The manufacture, and verification of purchased product of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

The manufacture of subassemblies and components for delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, and neurosurgical aspiration devices.



NSAI

Annex to Certificate Number: MD19.4277

Facility Locations, Scope and Activities

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

Scope:

The manufacture of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

The manufacture of subassemblies and components for delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, and neurosurgical aspiration devices.

One Penumbra Place, Building 1431, Alameda, CA 94502 USA
File No.: MD19.4277/M

Scope:

The design and development of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

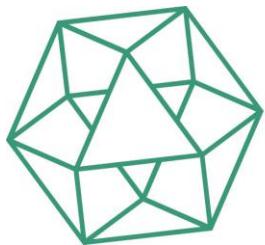
The evaluation of returned devices.

6262 Patterson Pass Road, Suite A & E/F, Livermore, CA 94550 USA
File No.: MD19.4277/F

Scope:

The verification of purchased product, and distribution of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

The distribution of subassemblies and components for delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, and neurosurgical aspiration devices.



NSAI

Annex to Certificate Number: MD19.4277

Facility Locations, Scope and Activities

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

Scope:

The distribution of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

The distribution of subassemblies and components for delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, and neurosurgical aspiration devices.

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

Scope:

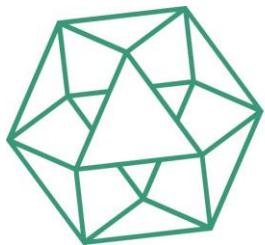
The manufacturing and verification of purchased product of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.

The manufacturing of subassemblies and components for delivery and aspiration catheters, separators, revascularization devices, embolization implants and neurosurgical aspiration devices.

1070 South 3800 West, Suites 500 and 700, Salt Lake City, UT 84104, USA
File No.: MD19.4277/K

Scope:

The verification of purchased product, repackaging/relabeling, and distribution of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, and active aspiration systems.



NSAI

Annex to Certificate Number: MD19.4277

Facility Locations, Scope and Activities

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

Scope:

The distribution of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, active aspiration systems, and third party manufactured neurosurgical, intravascular access, and treatment devices.

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

Scope:

The distribution and customer service of medical devices for the treatment of neuro, peripheral, and cardiovascular diseases including delivery catheters, aspiration catheters, separators, revascularization devices, embolization implants, neurosurgical aspirations devices, active aspiration systems, and third party manufactured neurosurgical, intravascular access, and treatment devices.

Verified by:
Director of Certification