

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: Michaela Mahl 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

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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