

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: Thrombectomy suction catheter
Product Trade Name: Penumbra System®
Products: See Attachment(s)

Classification: Reperfusion Catheter, Separator and 3D Revascularization Device:
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: Reperfusion Catheter, Separator and 3D Revascularization Device:
58173 - Thrombectomy suction catheter
Aspiration Tubing:
16779 - Aspiration Tubing: Surgical irrigation tubing/ single-use

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 (252.711, 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 (252.711, expiration date 26 May 2024), issued by NSAI (Dublin, Ireland, CE 0050).

Signature:



Date:

18 Feb 2021

Name &
Title:

Michaela Mahl
Senior Manager Regulatory Affairs

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Product List: "Penumbra System" (Class III, Rule 6)

Catalog Number	Description
PSC054	Reperfusion Catheter 054 straight, 132
PSC054L127	Reperfusion Catheter 054 straight, 127
PSC054L125	Reperfusion Catheter 054 straight, 125
PSC054MP127	Reperfusion Catheter 054 MP shape, 127
PSC054MP125	Reperfusion Catheter 054 MP shape, 125
PSC041	Reperfusion Catheter 041
PSC032	Reperfusion Catheter 032
PSC026	Reperfusion Catheter 026
4MAXC	Reperfusion Catheter 4MAX straight, 139
4MAXC130	Reperfusion Catheter 4MAX straight, 130
4MAXC125	Reperfusion Catheter 4MAX straight, 125
4MAXCMP	Reperfusion Catheter 4MAX MP shape, 139
4MAXCMP130	Reperfusion Catheter 4MAX MP shape, 130
4MAXCMP125	Reperfusion Catheter 4MAX MP shape, 125
3MAXC	Reperfusion Catheter 3MAX, 153
3MAXC	Reperfusion Catheter 3MAX, 160
PSC054	Reperfusion Catheter 5MAX, 132
PSC054L127	Reperfusion Catheter 5MAX, 127
PSC054L125	Reperfusion Catheter 5MAX, 125
PSC054L115	Reperfusion Catheter 5MAX, 115
5MAXACE132	Reperfusion Catheter 5MAX ACE / ACE 60, 132
5MAXACE127	Reperfusion Catheter 5MAX ACE / ACE 60, 127
5MAXACE125	Reperfusion Catheter 5MAX ACE / ACE 60, 125
5MAXACE115	Reperfusion Catheter 5MAX ACE / ACE 60, 115
5MAXACE064	Reperfusion Catheter ACE 64, 132
5MAXACE064L127	Reperfusion Catheter ACE 64, 127
5MAXACE064L125	Reperfusion Catheter ACE 64, 125
5MAXACE064L120	Reperfusion Catheter ACE 64, 120
5MAXACE064L115	Reperfusion Catheter ACE 64, 115
5MAXACE068	Reperfusion Catheter ACE 68, 132
5MAXACE068L127	Reperfusion Catheter ACE 68, 127
5MAXACE068L125	Reperfusion Catheter ACE 68, 125
5MAXACE068L120	Reperfusion Catheter ACE 68, 120
5MAXACE068L115	Reperfusion Catheter ACE 68, 115
5MAXJETDL139	Reperfusion Catheter Penumbra JET D, 139
5MAXJETD	Reperfusion Catheter Penumbra JET D, 138
5MAXJETDL137	Reperfusion Catheter Penumbra JET D, 137
5MAXJETDL136	Reperfusion Catheter Penumbra JET D, 136
5MAXJETDL135	Reperfusion Catheter Penumbra JET D, 135
5MAXJET7	Reperfusion Catheter Penumbra JET 7, 132
5MAXJET7L127	Reperfusion Catheter Penumbra JET 7, 127
5MAXJET7L125	Reperfusion Catheter Penumbra JET 7, 125
5MAXJET7L120	Reperfusion Catheter Penumbra JET 7, 120
5MAXJET7L115	Reperfusion Catheter Penumbra JET 7, 115

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Catalog Number	Description
PSS054	Separator 054
PSS041	Separator 041
PSS032	Separator 032
PSS026	Separator 026
PSF054	Separator Flex 054 / 5MAX
PSF041	Separator Flex 041 / 4MAX
PSF032	Separator Flex 032
PSF026	Separator Flex 026
3MAXS	Separator 3MAX
PSS3D	Separator 3D
PSC054KIT	Reperfusion Catheter 054 straight, 132 - KIT
PSC054L127KIT	Reperfusion Catheter 054 straight, 127 - KIT
PSC054L125KIT	Reperfusion Catheter 054 straight, 125 - KIT
PSC054MP127KIT	Reperfusion Catheter 054 MP shape, 127 - KIT
PSC054MP125KIT	Reperfusion Catheter 054 MP shape, 125 - KIT
PSC041KIT	Reperfusion Catheter 041 - KIT
PSC032KIT	Reperfusion Catheter 032 - KIT
PSC026KIT	Reperfusion Catheter 026 - KIT
4MAXCKIT	Reperfusion Catheter 4MAX straight, 139 - KIT
4MAXC130KIT	Reperfusion Catheter 4MAX straight, 130 - KIT
4MAXC125KIT	Reperfusion Catheter 4MAX straight, 125 - KIT
4MAXCMPKIT	Reperfusion Catheter 4MAX MP shape, 139 - KIT
4MAXCMP130KIT	Reperfusion Catheter 4MAX MP shape, 130 - KIT
4MAXCMP125KIT	Reperfusion Catheter 4MAX MP shape, 125 - KIT
3MAXCKIT	Reperfusion Catheter 3MAX, 153 - KIT
3MAXCKIT	Reperfusion Catheter 3MAX, 160 - KIT
PSC054KIT	Reperfusion Catheter 5MAX, 132 - KIT
PSC054L127KIT	Reperfusion Catheter 5MAX, 127 - KIT
PSC054L125KIT	Reperfusion Catheter 5MAX, 125 - KIT
PSC054L115KIT	Reperfusion Catheter 5MAX, 115 - KIT
5MAXACE132KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 132 - KIT
5MAXACE127KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 127 - KIT
5MAXACE125KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 125 - KIT
5MAXACE115KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 115 - KIT
5MAXACE064KIT	Reperfusion Catheter ACE 64, 132 - KIT
5MAXACE064L127KIT	Reperfusion Catheter ACE 64, 127 - KIT
5MAXACE064L125KIT	Reperfusion Catheter ACE 64, 125 - KIT
5MAXACE064L120KIT	Reperfusion Catheter ACE 64, 120 - KIT
5MAXACE064L115KIT	Reperfusion Catheter ACE 64, 115 - KIT
5MAXACE068KIT	Reperfusion Catheter ACE 68, 132 - KIT
5MAXACE068L127KIT	Reperfusion Catheter ACE 68, 127 - KIT
5MAXACE068L125KIT	Reperfusion Catheter ACE 68, 125 - KIT
5MAXACE068L120KIT	Reperfusion Catheter ACE 68, 120 - KIT
5MAXACE068L115KIT	Reperfusion Catheter ACE 68, 115 - KIT
5MAXJETDL139KIT	Reperfusion Catheter Penumbra JET D, 139 - KIT
5MAXJETDKIT	Reperfusion Catheter Penumbra JET D, 138 - KIT
5MAXJETDL137KIT	Reperfusion Catheter Penumbra JET D, 137 - KIT
5MAXJETDL136KIT	Reperfusion Catheter Penumbra JET D, 136 - KIT

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Catalog Number	Description
5MAXJETDL135KIT	Reperfusion Catheter Penumbra JET D, 135 - KIT
5MAXJET7KIT	Reperfusion Catheter Penumbra JET 7, 132 - KIT
5MAXJET7L127KIT	Reperfusion Catheter Penumbra JET 7, 127 - KIT
5MAXJET7L125KIT	Reperfusion Catheter Penumbra JET 7, 125 - KIT
5MAXJET7L120KIT	Reperfusion Catheter Penumbra JET 7, 120 - KIT
5MAXJET7L115KIT	Reperfusion Catheter Penumbra JET 7, 115 - KIT
PSR3D	3D Revascularization Device

(Class IIa, Rule 2)

PST1	Aspiration Tubing
PST2	MAX Aspiration Tubing
PST3	Hi-Flow Aspiration Tubing

End of Product List