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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 739816 R000

Manufacturer: Penumbra, Inc.

Address:
One Penumbra Place
Alameda
California
94502
USA

Single Registration Number: US-MF-000008514

EU Authorised Representative: Penumbra Europe GmbH

Address:
Am Borsigturm, 44
13507 Berlin
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-11-30**

Current Issue Date: **2024-05-29**

Starting Validity Date: **2024-05-29**

Expiry Date: **2026-11-29**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Penumbra Embolization Coil System	See MDR 739883

Class III	Intended purpose
INDIGO Aspiration System	See MDR 739880
INDIGO CAT RX Aspiration System	See MDR 778752
Penumbra Access Catheter System	See MDR 778754
Penumbra Delivery Microcatheters	See MDR 781037
Penumbra System	See MDR 763182

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Aspiration Tubing	Class IIa
Penumbra Aspiration Pumps	Class IIa
Penumbra Embolization Coil Detachment Handles	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-30	3328694	Issued
2022-07-22	3715610	Supplemented – Addition of Penumbra System device
2023-03-29	3871422	Supplemented – Addition of Penumbra Embolization Coil System and associated Detachment Handles
2023-12-13	30026642	Supplemented – Addition of INDIGO CAT RX Aspiration System and Penumbra Aspiration Pumps
2024-03-27	30095745	Supplemented – Addition of Penumbra Delivery Microcatheters
Current	30169191	Supplemented – Addition of Aspiration Tubing and Penumbra Access Catheter System

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