



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

Current Issue Date: **2024-05-29** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





# EU Quality Management System Certificate

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

## MDR 739816 R000

#### **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	B (A) 10
INDIGO CAT RX Aspiration System	See MDR 778752	The Carrie
Penumbra Access Catheter System	See MDR 778754	
Penumbra Delivery Microcatheters	See MDR 781037	
Penumbra System	See MDR 763182	S Gar

### 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.

First Issue Date: 2021-11-30 Starting Validity Date: 2024-05-29

Current Issue Date: **2024-05-29** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 2 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.





# EU Quality Management System Certificate

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

## MDR 739816 R000

### **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

First Issue Date: 2021-11-30 Starting Validity Date: 2024-05-29

Current Issue Date: **2024-05-29** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 3 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.