By Royal Charter

# 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 and Class IIb implantable devices an 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 Medical Devices

First Issued: **2021-11-30** Date: **2022-07-22** Expiry Date: **2026-11-29**

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### Device Schedule: Class III and Class IIb devices

| Class III | Intended purpose |
|---|---|
| INDIGO Aspiration System | See MDR 739880 |
| Penumbra System | See MDR 763182 |

First Issued: **2021-11-30** Date: **2022-07-22** Expiry Date: **2026-11-29**

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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.

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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 |
| Current | 3715610 | Supplemented – Addition of Penumbra System device |

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## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

**MDR 739816 R000**

Date: **2022-07-22**

| Critical Subcontractor/Crucial Supplier | Service(s) supplied |
|---|---|
| Penumbra Inc.<br>630 Roseville Parkway<br>Roseville<br>CA<br>95747<br>USA | **Manufacture** |
| Sterigenics US, LLC<br>5725 W. Harold Gatty Drive<br>Salt Lake City<br>Utah<br>84116<br>USA | **ETO Sterilization** |
| Sterigenics US, LLC<br>4900 Gifford Avenue<br>Los Angeles<br>California<br>90058<br>USA | **ETO Sterilization** |

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