EU Declaration of Conformity

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer, Penumbra, Inc.

Manufacturer:	Penumbra, Inc. One Penumbra Place Alameda, CA 94502, USA SRN: US-MF-000008514
Authorized EC Representative:	Penumbra Europe GmbH Am Borsigturm 44 13507 Berlin, Germany SRN: DE-AR-000004997
Design:	Penumbra, Inc. One Penumbra Place Alameda, CA 94502, USA
Manufacturing Facility:	Penumbra, Inc. One Penumbra Place Alameda, CA 94502, USA Penumbra, Inc. 630 Roseville Parkway Roseville, CA 95747, USA
Product Category:	Catheter, Embolectomy
Product Trade Name:	INDIGO™ Aspiration System
Product Identification:	See enclosed Attachment 1
Risk Classification:	<u>INDIGO CAT RX Aspiration Catheter & Separator 4:</u> Class III, Rule 6, Bullet 1 based on EU MDR 2017-745 – Annex VIII [Classification Rules – Chapter III] <u>INDIGO Aspiration Tubing:</u> Class IIa, Rule 2 based on EU MDR 2017-745 - Annex VIII [Classification Rules - Chapter III]
Intended Purpose:	The INDIGO Aspiration System is designed to remove emboli and thrombi from the vasculature using continuous aspiration.
Basic UDI DI:	<u>INDIGO CAT RX Aspiration System</u> 081454801CRXES
Technical Standards/Specifications:	See enclosed Attachment 2

Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands SIN: 2797
Selected conformity assessment procedure:	EU MDR 2017-745 – Annex IX

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of EU MDR 2017-745, as transposed into the national laws of the EU member states.

This declaration is supported by:

- EU Quality Management System Certificate: MDR 739816, expires on 29-NOV-2026.
- Technical Documentation Assessment Certificate Number: MDR 778752, expires on 12-DEC-2028.

Signature:

DocuSigned by:
Samyukta Rangachari
Signer Name: Samyukta Rangachari
Signing Reason: I approve this document
Signing Time: 12/18/2023 | 11:00:28 AM PST
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Print Name & Title: Samyukta Rangachari, Regulatory Affairs Specialist II

Check here if signing on behalf of the PRRC ☒

Place of Issue: Alameda, California

Date of Issue: 18-DEC-2023
(DD-MMM-YYYY)

ATTACHMENT 1 TO THE EU DECLARATION OF CONFORMITY

Product List: "INDIGO™ Aspiration System" (Class III, Rule 6)

Catalog No.	Device Name	Basic UDI-DI
CATRXKIT120	044 Coronary Aspiration Catheter 120cm Kit	081454801CTRXAF
CATRXKIT125	044 Coronary Aspiration Catheter 125cm Kit	
CATRXKIT130	044 Coronary Aspiration Catheter 130cm Kit	
CATRXKIT135	044 Coronary Aspiration Catheter 135cm Kit	
CATRXKIT	044 Coronary Aspiration Catheter 140cm Kit	
CATRXKIT145	044 Coronary Aspiration Catheter 145cm Kit	
CATRXKIT150	044 Coronary Aspiration Catheter 150cm Kit	
CATRXKIT155	044 Coronary Aspiration Catheter 155cm Kit	
CATRXKIT160	044 Coronary Aspiration Catheter 160cm Kit	
SEPC4	Separator 4	081454801SC4DP

End of Product List

ATTACHMENT 2 TO THE EU DECLARATION OF CONFORMITY

Standards Listing

Note: As the EU MDR's Annex I, Item 1 (General Safety & Performance Requirements) requires 'state of the art,' Penumbra, Inc. follows the most current version of a standard, even if it has not been harmonized under the EU MDR 2017-745 based on gap analysis.

Standard	Title
BS EN ISO 13485:2016+A11 2021	Medical Devices - Quality management systems - requirement for regulatory purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
BS EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
BS EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
BS EN ISO 10993-7:2008/ AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
BS EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
BS EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
BS EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
BS EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 14155:2020[1]	Clinical investigation of medical devices for human subjects - Good clinical practice
BS EN 20594-1:1994/A1:1997 [= ISO 594-1:1986]	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
ISO 594-2:1998	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
BS EN ISO 10555-1:2013+A1:2017	lntravascular catheters - Sterile and single-use catheters - Part 1: General requirements
BS EN 62366-1:2015 +A1:2020[2]	Medical Devices - Application of Usability Engineering to Medical Devices

[1] All clinical investigations which were conducted and completed prior to 2021 are fully in compliance with the applicable EN ISO 14155 versions at that time.
[2] All testing conducted and completed prior to February 2021 are fully in compliance with the IEC 62366 [EN 62366] version applicable at that time.

ATTACHMENT 2 TO THE EU DECLARATION OF CONFORMITY

Standard	Title
BS EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices
BS EN ISO 11135:2014+A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11138-2:2017	Sterilization of health care products - Biological Indicators - Part 2: Biological Indicators for Ethylene Oxide Sterilization Processes
BS EN ISO 11737-1:2018+A1:2021	Sterilization of Medical Devices - Microbiological Methods - Part 1: Determination of a Population of Microorganisms on Products
BS EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
BS EN ISO 11607-1:2020[3] & BS EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems; Part 2: Validation requirements for forming, sealing and assembly processes
BS EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
USP <161>:2018	Medical Devices - Bacterial Endotoxin and Pyrogen Tests
USP <85>:2018	Bacterial Endotoxins Test
ANSI/AAMI ST72:2019	Bacterial Endotoxins - Test methods, routine monitoring, and alternatives to batch testing
AAMI TIR42:2010	Evaluation of particulates associated with vascular medical devices
ASTM F1980:2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4169:2016[4]	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1929:2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096:2011	Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)

[3] All testing conducted and completed prior to February 2021 are fully in compliance with the BS EN ISO 11607-1 version applicable at that time.
[4] All testing conducted and completed prior to September 2016 are fully in compliance with the ASTM D4169 version applicable at that time.

ATTACHMENT 2 TO THE EU DECLARATION OF CONFORMITY

Standard	Title
ASTM D6499:2018	Standard Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products
ASTM F756:2017	Standard Practice for Assessment of Hemolytic Properties of Materials
ASTM F640-2020	Standard Test Methods for Determining Radiopacity for Medical Use
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials