

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 778752 R000

Manufacturer: Penumbra Inc.

Address:

One Penumbra Place
Alameda
California
94502
USA

Single Registration Number: US-MF-000008514

EU Authorised Representative: Penumbra Europe GmbH

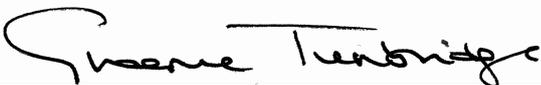
Address:

Am Borsigturm 44
13507 Berlin
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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 Issue Date: **2023-12-13**

Current Issue Date: **2023-12-13**

Starting Validity Date: **2023-12-13**

Expiry Date: **2028-12-12**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The INDIGO CAT RX Aspiration System is designed to remove emboli and thrombi from the vasculature using continuous aspiration.

Risk Classification: Class III

Basic UDI-DI:

Device	Basic UDI-DI
INDIGO CAT RX Catheter and Tubing – Kit Configuration	081454801CTRAXAF
INDIGO Separator 4	081454801SC4DP

Device Name	Model	Type (Codes as per (EU) 2017/2185)
044 Coronary Aspiration Catheter 120cm Kit	CATRXKIT120	MDN1202
044 Coronary Aspiration Catheter 125cm Kit	CATRXKIT125	MDN1202
044 Coronary Aspiration Catheter 130cm Kit	CATRXKIT130	MDN1202
044 Coronary Aspiration Catheter 135cm Kit	CATRXKIT135	MDN1202
044 Coronary Aspiration Catheter 140cm Kit	CATRXKIT	MDN1202
044 Coronary Aspiration Catheter 145cm Kit	CATRXKIT145	MDN1202
044 Coronary Aspiration Catheter 150cm Kit	CATRXKIT150	MDN1202
044 Coronary Aspiration Catheter 155cm Kit	CATRXKIT155	MDN1202
044 Coronary Aspiration Catheter 160cm Kit	CATRXKIT160	MDN1202
Separator 4	SEPC4	MDN1202

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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
Current	3767972	Issued



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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.