

EU Technical Documentation Assessment Certificate

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

MDR 739880 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-11-30**

Date: **2021-11-30**

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

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Device Schedule:

Risk Classification: Class III

Intended Purpose: The INDIGO Aspiration System is designed to remove thrombus from the vasculature using mechanical aspiration.

Basic UDI-DI: 081454801INDIGOSYSTEMYF

Device Name	Model	Type (Codes as per (EU) 2017/2185)
Aspiration Catheters		
CAT3	Aspiration Catheter 3, Straight, 150cm	MDN 1202
CAT5L125	Aspiration Catheter 5, Straight, 125cm	
CAT5L127	Aspiration Catheter 5, Straight, 127cm	
CAT5	Aspiration Catheter 5, Straight, 132cm	
CAT5MP125	Aspiration Catheter 5, MP, 125cm	
CAT5MP127	Aspiration Catheter 5, MP, 127cm	
CAT6STR30	Aspiration Catheter 6, Straight, 30cm	
CAT6STR40	Aspiration Catheter 6, Straight, 40cm	
CAT6STR50	Aspiration Catheter 6, Straight, 50cm	
CAT6STR60	Aspiration Catheter 6, Straight, 60cm	
CAT6STR70	Aspiration Catheter 6, Straight, 70cm	
CAT6STR80	Aspiration Catheter 6, Straight, 80cm	
CAT6STR90	Aspiration Catheter 6, Straight, 90cm	
CAT6STR100	Aspiration Catheter 6, Straight, 100cm	
CAT6STR110	Aspiration Catheter 6, Straight, 110cm	
CAT6STR115	Aspiration Catheter 6, Straight, 115cm	
CAT6STR120	Aspiration Catheter 6, Straight, 120cm	
CAT6STR125	Aspiration Catheter 6, Straight, 125cm	
CAT6STR132	Aspiration Catheter 6, Straight, 132cm	
CAT6	Aspiration Catheter 6, Straight, 135cm	
CAT6MP30	Aspiration Catheter 6, MP, 30cm	

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Device Name	Model	Type (Codes as per (EU) 2017/2185)
Aspiration Catheters		
CAT6MP40	Aspiration Catheter 6, MP, 40cm	MDN 1202
CAT6MP50	Aspiration Catheter 6, MP, 50cm	
CAT6MP60	Aspiration Catheter 6, MP, 60cm	
CAT6MP70	Aspiration Catheter 6, MP, 70cm	
CAT6MP80	Aspiration Catheter 6, MP, 80cm	
CAT6MP90	Aspiration Catheter 6, MP, 90cm	
CAT6MP100	Aspiration Catheter 6, MP, 100cm	
CAT6MP110	Aspiration Catheter 6, MP, 110cm	
CAT6MP115	Aspiration Catheter 6, MP, 115cm	
CAT6MP120	Aspiration Catheter 6, MP, 120cm	
CAT6MP125	Aspiration Catheter 6, MP, 125cm	
CAT6MP132	Aspiration Catheter 6, MP, 132cm	
CAT6MP135	Aspiration Catheter 6, MP, 135cm	
CAT8STR30	Aspiration Catheter 8, Straight, 30cm	
CAT8STR40	Aspiration Catheter 8, Straight, 40cm	
CAT8STR50	Aspiration Catheter 8, Straight, 50cm	
CAT8STR60	Aspiration Catheter 8, Straight, 60cm	
CAT8STR70	Aspiration Catheter 8, Straight, 70cm	
CAT8STR80	Aspiration Catheter 8, Straight, 80cm	
CAT8STR85	Aspiration Catheter 8, Straight, 85cm	
CAT8STR90	Aspiration Catheter 8, Straight, 90cm	
CAT8STR95	Aspiration Catheter 8, Straight, 95cm	
CAT8STR100	Aspiration Catheter 8, Straight, 100cm	
CAT8STR110	Aspiration Catheter 8, Straight, 110cm	
CAT8STR115	Aspiration Catheter 8, Straight, 115cm	
CAT8TORQ30	Aspiration Catheter 8, TORQ, 30cm	
CAT8TORQ40	Aspiration Catheter 8, TORQ, 40cm	
CAT8TORQ50	Aspiration Catheter 8, TORQ, 50cm	
CAT8TORQ60	Aspiration Catheter 8, TORQ, 60cm	
CAT8TORQ70	Aspiration Catheter 8, TORQ, 70cm	

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Device Name	Model	Type (Codes as per (EU) 2017/2185)
Aspiration Catheters		
CAT8TORQ80	Aspiration Catheter 8, TORQ, 80cm	MDN 1202
CAT8TORQ85	Aspiration Catheter 8, TORQ, 85cm	
CAT8TORQ95	Aspiration Catheter 8, TORQ, 95cm	
CAT8TORQ110	Aspiration Catheter 8, TORQ, 110cm	
CAT8XTORQ90	Aspiration Catheter 8, XTORQ, 90cm	
CAT8XTORQ100	Aspiration Catheter 8, XTORQ, 100cm	
CAT8XTORQ115	Aspiration Catheter 8, XTORQ, 115cm	
Separator		
SEP3	Separator 3, 190cm	MDN 1203
SEP5	Separator 5, 175cm	
SEP6	Separator 6, 175cm	
SEP7D	Separator 7D, 90cm	
SEP7130	Separator 7, 175cm	
SEP7	Separator 7, 190cm	
SEP8	Separator 8, 150cm	
SEPD	Separator D, 90cm	
SEP12	Separator 12, 150cm	
SEP1250	Separator 12, 90cm	
Aspiration Catheter + Aspiration Tubing - KITS		
CAT3KIT	Aspiration Catheter 3, Straight, 150cm - KIT	MDN 1202
CAT5L125KIT	Aspiration Catheter 5, Straight, 125cm - KIT	
CAT5L127KIT	Aspiration Catheter 5, Straight, 127cm - KIT	
CAT5KIT	Aspiration Catheter 5, Straight, 132cm - KIT	
CAT5MP125KIT	Aspiration Catheter 5, MP, 125cm - KIT	
CAT5MP127KIT	Aspiration Catheter 5, MP, 127cm - KIT	
CAT6STR30KIT	Aspiration Catheter 6, Straight, 30cm - KIT	
CAT6STR40KIT	Aspiration Catheter 6, Straight, 40cm - KIT	
CAT6STR50KIT	Aspiration Catheter 6, Straight, 50cm - KIT	
CAT6STR60KIT	Aspiration Catheter 6, Straight, 60cm - KIT	
CAT6STR70KIT	Aspiration Catheter 6, Straight, 70cm - KIT	

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Device Name	Model	Type (Codes as per (EU) 2017/2185)
Aspiration Catheter + Aspiration Tubing - KITS		
CAT6STR80KIT	Aspiration Catheter 6, Straight, 80cm - KIT	MDN 1202
CAT6STR90KIT	Aspiration Catheter 6, Straight, 90cm - KIT	
CAT6STR100KIT	Aspiration Catheter 6, Straight, 100cm - KIT	
CAT6STR110KIT	Aspiration Catheter 6, Straight, 110cm - KIT	
CAT6STR115KIT	Aspiration Catheter 6, Straight, 115cm - KIT	
CAT6STR120KIT	Aspiration Catheter 6, Straight, 120cm - KIT	
CAT6STR125KIT	Aspiration Catheter 6, Straight, 125cm - KIT	
CAT6STR132KIT	Aspiration Catheter 6, Straight, 132cm - KIT	
CAT6KIT	Aspiration Catheter 6, Straight, 135cm - KIT	
CAT6MP30KIT	Aspiration Catheter 6, MP, 30cm - KIT	
CAT6MP40KIT	Aspiration Catheter 6, MP, 40cm - KIT	
CAT6MP50KIT	Aspiration Catheter 6, MP, 50cm - KIT	
CAT6MP60KIT	Aspiration Catheter 6, MP, 60cm - KIT	
CAT6MP70KIT	Aspiration Catheter 6, MP, 70cm - KIT	
CAT6MP80KIT	Aspiration Catheter 6, MP, 80cm - KIT	
CAT6MP90KIT	Aspiration Catheter 6, MP, 90cm - KIT	
CAT6MP100KIT	Aspiration Catheter 6, MP, 100cm - KIT	
CAT6MP110KIT	Aspiration Catheter 6, MP, 110cm - KIT	
CAT6MP115KIT	Aspiration Catheter 6, MP, 115cm - KIT	
CAT6MP120KIT	Aspiration Catheter 6, MP, 120cm - KIT	
CAT6MP125KIT	Aspiration Catheter 6, MP, 125cm - KIT	
CAT6MP132KIT	Aspiration Catheter 6, MP, 132cm - KIT	
CAT6MP135KIT	Aspiration Catheter 6, MP, 135cm - KIT	
CAT7STR50KIT	Aspiration Catheter 7, Straight, 50cm - KIT	
CAT7STR130KIT	Aspiration Catheter 7, Straight, 130cm - KIT	
CAT7STR160KIT	Aspiration Catheter 7, Straight, 160cm - KIT	
CAT7TORQ50KIT	Aspiration Catheter 7, TORQ, 50cm - KIT	
CAT7TORQ130KIT	Aspiration Catheter 7, TORQ, 130cm - KIT	
CAT7TORQ160KIT	Aspiration Catheter 7, TORQ, 160cm - KIT	
CAT7DKIT	Aspiration Catheter 7D, XTORQ, 50cm - KIT	

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Aspiration Catheter + Aspiration Tubing - KITS		
CAT7XTORQ130KIT	Aspiration Catheter 7, XTORQ, 130cm - KIT	MDN 1202
CAT7XTORQ160KIT	Aspiration Catheter 7, XTORQ, 160cm - KIT	
CAT8STR30KIT	Aspiration Catheter 8, Straight, 30cm - KIT	
CAT8STR40KIT	Aspiration Catheter 8, Straight, 40cm - KIT	
CAT8STR50KIT	Aspiration Catheter 8, Straight, 50cm - KIT	
CAT8STR60KIT	Aspiration Catheter 8, Straight, 60cm - KIT	
CAT8STR70KIT	Aspiration Catheter 8, Straight, 70cm - KIT	
CAT8STR80KIT	Aspiration Catheter 8, Straight, 80cm - KIT	
CAT8STR85KIT	Aspiration Catheter 8, Straight, 85cm - KIT	
CAT8STR90KIT	Aspiration Catheter 8, Straight, 90cm - KIT	
CAT8STR95KIT	Aspiration Catheter 8, Straight, 95cm - KIT	
CAT8STR100KIT	Aspiration Catheter 8, Straight, 100cm - KIT	
CAT8STR110KIT	Aspiration Catheter 8, Straight, 110cm - KIT	
CAT8STR115KIT	Aspiration Catheter 8, Straight, 115cm - KIT	
CAT8TORQ30KIT	Aspiration Catheter 8, TORQ, 30cm - KIT	
CAT8TORQ40KIT	Aspiration Catheter 8, TORQ, 40cm - KIT	
CAT8TORQ50KIT	Aspiration Catheter 8, TORQ, 50cm - KIT	
CAT8TORQ60KIT	Aspiration Catheter 8, TORQ, 60cm - KIT	
CAT8TORQ70KIT	Aspiration Catheter 8, TORQ, 70cm - KIT	
CAT8TORQ80KIT	Aspiration Catheter 8, TORQ, 80cm - KIT	
CAT8TORQ85KIT	Aspiration Catheter 8, TORQ, 85cm - KIT	
CAT8TORQ95KIT	Aspiration Catheter 8, TORQ, 95cm - KIT	
CAT8TORQ110KIT	Aspiration Catheter 8, TORQ, 110cm - KIT	
CAT8XTORQ90KIT	Aspiration Catheter 8, XTORQ, 90cm - KIT	
CAT8XTORQ100KIT	Aspiration Catheter 8, XTORQ, 100cm - KIT	
CAT8XTORQ115KIT	Aspiration Catheter 8, XTORQ, 115cm - KIT	
CATD30STR	Aspiration Catheter D, Straight, 30cm - KIT	
CATD35STR	Aspiration Catheter D, Straight, 35cm - KIT	
CATD40STR	Aspiration Catheter D, Straight, 40cm - KIT	
CATD45STR	Aspiration Catheter D, Straight, 45cm - KIT	

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Aspiration Catheter + Aspiration Tubing - KITS		
CATD50STR	Aspiration Catheter D, Straight, 50cm - KIT	MDN 1202
CATD30	Aspiration Catheter D, MP, 30cm - KIT	
CATD35	Aspiration Catheter D, MP, 35cm - KIT	
CATD40	Aspiration Catheter D, MP, 40cm - KIT	
CATD45	Aspiration Catheter D, MP, 45cm - KIT	
CATD	Aspiration Catheter D, MP, 50cm - KIT	
CAT12STR30KIT	Aspiration Catheter 12, Straight, 30cm - KIT	
CAT12STR40KIT	Aspiration Catheter 12, Straight, 40cm - KIT	
CAT12STR50KIT	Aspiration Catheter 12, Straight, 50cm - KIT	
CAT12STR60KIT	Aspiration Catheter 12, Straight, 60cm - KIT	
CAT12STR70KIT	Aspiration Catheter 12, Straight, 70cm - KIT	
CAT12STR80KIT	Aspiration Catheter 12, Straight, 80cm - KIT	
CAT12STR85KIT	Aspiration Catheter 12, Straight, 85cm - KIT	
CAT12STR90KIT	Aspiration Catheter 12, Straight, 90cm - KIT	
CAT12STR95KIT	Aspiration Catheter 12, Straight, 95cm - KIT	
CAT12STR100KIT	Aspiration Catheter 12, Straight, 100cm - KIT	
CAT12STR110KIT	Aspiration Catheter 12, Straight, 110cm - KIT	
CAT12STR115KIT	Aspiration Catheter 12, Straight, 115cm - KIT	
CAT12XTORQ30KIT	Aspiration Catheter 12, XTORQ, 30cm - KIT	
CAT12XTORQ40KIT	Aspiration Catheter 12, XTORQ, 40cm - KIT	
CAT12XTORQ50KIT	Aspiration Catheter 12, XTORQ, 50cm - KIT	
CAT12XTORQ60KIT	Aspiration Catheter 12, XTORQ, 60cm - KIT	
CAT12XTORQ70KIT	Aspiration Catheter 12, XTORQ, 70cm - KIT	
CAT12XTORQ80KIT	Aspiration Catheter 12, XTORQ, 80cm - KIT	
CAT12XTORQ85KIT	Aspiration Catheter 12, XTORQ, 85cm - KIT	
CAT12XTORQ90KIT	Aspiration Catheter 12, XTORQ, 90cm - KIT	
CAT12XTORQ95KIT	Aspiration Catheter 12, XTORQ, 95cm - KIT	
CAT12XTORQ100KIT	Aspiration Catheter 12, XTORQ, 100cm - KIT	
CAT12XTORQ110KIT	Aspiration Catheter 12, XTORQ, 110cm - KIT	
CAT12XTORQ115KIT	Aspiration Catheter 12, XTORQ, 115cm - KIT	

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Aspiration Catheter + Aspiration Tubing - KITS		
CAT12HTORQ30KIT	Aspiration Catheter 12, HTORQ, 30cm - KIT	MDN 1202
CAT12HTORQ40KIT	Aspiration Catheter 12, HTORQ, 40cm - KIT	
CAT12HTORQ50KIT	Aspiration Catheter 12, HTORQ, 50cm - KIT	
CAT12HTORQ60KIT	Aspiration Catheter 12, HTORQ, 60cm - KIT	
CAT12HTORQ70KIT	Aspiration Catheter 12, HTORQ, 70cm - KIT	
CAT12HTORQ80KIT	Aspiration Catheter 12, HTORQ, 80cm - KIT	
CAT12HTORQ85KIT	Aspiration Catheter 12, HTORQ, 85cm - KIT	
CAT12HTORQ90KIT	Aspiration Catheter 12, HTORQ, 90cm - KIT	
CAT12HTORQ95KIT	Aspiration Catheter 12, HTORQ, 95cm - KIT	
CAT12HTORQ100KIT	Aspiration Catheter 12, HTORQ, 100cm - KIT	
CAT12HTORQ110KIT	Aspiration Catheter 12, HTORQ, 110cm - KIT	
CAT12HTORQ115KIT	Aspiration Catheter 12, HTORQ, 115cm - KIT	
Aspiration Catheter + Lightning Aspiration Tubing - KITS		
LITNG7XTORQ130	Lightning 7, XTORQ, 130cm - KIT	MDA 0306
LITNG8STR85	Lightning 8, Straight, 85cm - KIT	
LITNG8TORQ85	Lightning 8, TORQ, 85cm - KIT	
LITNG8XTORQ115	Lightning 8, XTORQ, 115cm - KIT	
LITNG12XTORQ100	Lightning 12, XTORQ, 100cm - KIT	
LITNG12XTORQ115	Lightning 12, XTORQ, 115cm - KIT	
LITNG12HTORQ100	Lightning 12, HTORQ, 100cm - KIT	
LITNG12HTORQ115	Lightning 12, HTORQ, 115cm - KIT	

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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	3329040	Issued

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