

# EU Technical Documentation Assessment Certificate

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

## MDR 778754 R000

**Manufacturer:** Penumbra, Inc.

**Address:**

One Penumbra Place  
Alameda  
California  
94502  
USA

**Single Registration Number:** US-MF-000008514

**EU Authorised Representative:** Penumbra Europe GmbH

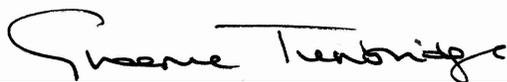
**Address:**

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 Global Regulatory & Quality

First Issue Date: **2024-05-29**

Current Issue Date: **2025-10-27**

Starting Validity Date: **2025-10-27**

Expiry Date: **2029-05-28**

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### Device Schedule:

#### Intended Purpose as per the Instructions for Use:

The Penumbra Access Catheter System is designed to provide a conduit for introduction of interventional devices to the peripheral and neurovascular anatomy.

The Element Vascular Access System is designed to provide a conduit for introduction of interventional devices to the peripheral anatomy.

**Risk Classification:** Class III

**Type** (Codes as per (EU) 2017/2185): MDN 1203

#### Basic UDI-DI:

System	
Penumbra Access Catheter System	081454801ACCESSY8
Components	
Delivery Catheter/Sheath	081454801DELIVERYP3
Select Catheter	081454801SELECT8U
Access Catheter System – Kits	081454801ACCESSKITW7

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Model	Device name
PND6F1056	6F Neuron 053 Delivery Catheter (105 cm/6 cm STR)
PND6F1056M	6F Neuron 053 Delivery Catheter (105 cm/6 cm MP)
PND6F10512	6F Neuron 053 Delivery Catheter (105 cm/12 cm STR)
PND6F10512M	6F Neuron 053 Delivery Catheter (105 cm/12 cm MP)
PND6F1156	6F Neuron 053 Delivery Catheter (115 cm/6 cm STR)
PND6F1156M	6F Neuron 053 Delivery Catheter (115 cm/6 cm MP)
PND6F11512	6F Neuron 053 Delivery Catheter (115 cm/12 cm STR)
PND6F11512M	6F Neuron 053 Delivery Catheter (115 cm/12 cm MP)
PND6F070956	6F Neuron 070 Delivery Catheter (95 cm/6 cm STR)
PND6F070956M	6F Neuron 070 Delivery Catheter (95 cm/6 cm MP)
PND6F0701058	6F Neuron 070 Delivery Catheter (105 cm/8 cm STR)
PND6F0701058M	6F Neuron 070 Delivery Catheter (105 cm/8 cm MP)
BMK6F95	6F Benchmark Delivery Catheter (95 cm STR)
BMK6F95M	6F Benchmark Delivery Catheter (95 cm MP)
BMK6F105	6F Benchmark Delivery Catheter (105 cm STR)

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BMK6F105M	6F Benchmark Delivery Catheter (105 cm MP)
BMK6F115	6F Benchmark Delivery Catheter (115 cm STR)
BMK6F115M	6F Benchmark Delivery Catheter (115 cm MP)
BMX7F95	7F BMX81 Delivery Catheter (95 cm STR)
BMX7F95M	7F BMX81 Delivery Catheter (95 cm MP)
BMX7F105	7F BMX81 Delivery Catheter (105 cm STR)
BMX7F105M	7F BMX81 Delivery Catheter (105 cm MP)
BMX7F115	7F BMX81 Delivery Catheter (115 cm STR)
BMX7F115M	7F BMX81 Delivery Catheter (115 cm MP)
PNML6F088704	6F Neuron MAX Long Sheath (70 cm STR)
PNML6F088704M	6F Neuron MAX Long Sheath (70 cm MP)
PNML6F088804	6F Neuron MAX Long Sheath (80 cm STR)
PNML6F088804M	6F Neuron MAX Long Sheath (80 cm MP)
PNML6F088904	6F Neuron MAX Long Sheath (90 cm STR)
PNML6F088904M	6F Neuron MAX Long Sheath (90 cm MP)
PNML6F0881004	6F Neuron MAX Long Sheath (100 cm STR)
PNML6F0881004M	6F Neuron MAX Long Sheath (100 cm MP)
BMX9680	8F BMX96 Delivery Catheter (80 cm STR)
BMX9690	8F BMX96 Delivery Catheter (90 cm STR)
BMX96100	8F BMX96 Delivery Catheter (100 cm STR)

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Model	Device name
43MWAY115	MIDWAY 43 Delivery Catheter (115 cm)
43MWAY120	MIDWAY 43 Delivery Catheter (120 cm)
43MWAY125	MIDWAY 43 Delivery Catheter (125 cm)
43MWAY127	MIDWAY 43 Delivery Catheter (127 cm)
43MWAY136	MIDWAY 43 Delivery Catheter (136 cm)
43MWAY138	MIDWAY 43 Delivery Catheter (138 cm)
43MWAY160	MIDWAY 43 Delivery Catheter (160 cm)
43MWAY162	MIDWAY 43 Delivery Catheter (162 cm)
43MWAY167	MIDWAY 43 Delivery Catheter (167 cm)
62MWAY115	MIDWAY 62 Delivery Catheter (115 cm)
62MWAY120	MIDWAY 62 Delivery Catheter (120 cm)
62MWAY125	MIDWAY 62 Delivery Catheter (125 cm)
62MWAY132	MIDWAY 62 Delivery Catheter (132 cm)
62MWAY138	MIDWAY 62 Delivery Catheter (138 cm)
62MWAY160	MIDWAY 62 Delivery Catheter (160 cm)
ELMNT17F13	Element 17F Vascular Access System (13 cm)
ELMNT17F33	Element 17F Vascular Access System (33 cm)
ELMNT17F45	Element 17F Vascular Access System (45 cm)
ELMNT17F65	Element 17F Vascular Access System (65 cm)
ELMNT17F70	Element 17F Vascular Access System (70 cm)

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ELMNT17F80	Element 17F Vascular Access System (80 cm)
PNS5F120SIM	5F Select Catheter (120 cm SIM)
PNS5F120H1	5F Select Catheter (120 cm H1)
PNS5F120BER	5F Select Catheter (120 cm BER)
PNS5F130SIM	5F Select Catheter (130 cm SIM)
PNS5F130H1	5F Select Catheter (130 cm H1)
PNS5F130BER	5F Select Catheter (130 cm BER)
PNS6F105SIM	6F Select Catheter (105 cm SIM)
PNS6F105H1	6F Select Catheter (105 cm H1)
PNS6F105BER	6F Select Catheter (105 cm BER)
PNS6F105SIMV	6F Select Catheter (105 cm SIM-V)
PNS6F125SIM	6F Select Catheter (125 cm SIM)
PNS6F125H1	6F Select Catheter (125 cm H1)
PNS6F125BER	6F Select Catheter (125 cm BER)
PNS6F125SIMV	6F Select Catheter (125 cm SIM-V)
BMK6F95BER120	6F Benchmark Delivery Catheter (95 cm STR) + 5F Select Catheter (120 cm BER)
BMK6F95H1120	6F Benchmark Delivery Catheter (95 cm STR) + 5F Select Catheter (120 cm H1)
BMK6F95SIM120	6F Benchmark Delivery Catheter (95 cm STR) + 5F Select Catheter (120 cm SIM)
BMK6F95MBER120	6F Benchmark Delivery Catheter (95 cm MP) + 5F Select Catheter (120 cm BER)
BMK6F95MH1120	6F Benchmark Delivery Catheter (95 cm MP) + 5F Select Catheter (120 cm H1)
BMK6F95MSIM120	6F Benchmark Delivery Catheter (95 cm MP) + 5F Select Catheter (120 cm SIM)

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Model	Device name
BMK6F95BER130	6F Benchmark Delivery Catheter (95 cm STR) + 5F Select Catheter (130 cm BER)
BMK6F95H1130	6F Benchmark Delivery Catheter (95 cm STR) + 5F Select Catheter (130 cm H1)
BMK6F95SIM130	6F Benchmark Delivery Catheter (95 cm STR) + 5F Select Catheter (130 cm SIM)
BMK6F95MBER130	6F Benchmark Delivery Catheter (95 cm MP) + 5F Select Catheter (130 cm BER)
BMK6F95MH1130	6F Benchmark Delivery Catheter (95 cm MP) + 5F Select Catheter (130 cm H1)
BMK6F95MSIM130	6F Benchmark Delivery Catheter (95 cm MP) + 5F Select Catheter (130 cm SIM)
BMK6F105BER130	6F Benchmark Delivery Catheter (105 cm STR) + 5F Select Catheter (130 cm BER)
BMK6F105H1130	6F Benchmark Delivery Catheter (105 cm STR) + 5F Select Catheter (130 cm H1)
BMK6F105SIM130	6F Benchmark Delivery Catheter (105 cm STR) + 5F Select Catheter (130 cm SIM)
BMK6F105MBER130	6F Benchmark Delivery Catheter (105 cm MP) + 5F Select Catheter (130 cm BER)
BMK6F105MH1130	6F Benchmark Delivery Catheter (105 cm MP) + 5F Select Catheter (130 cm H1)
BMK6F105MSIM130	6F Benchmark Delivery Catheter (105 cm MP) + 5F Select Catheter (130 cm SIM)
BMX7F95BER120	7F BMX81 Delivery Catheter (95 cm STR) + 5F Select Catheter (120 cm BER)
BMX7F95H1120	7F BMX81 Delivery Catheter (95 cm STR) + 5F Select Catheter (120 cm H1)
BMX7F95SIM120	7F BMX81 Delivery Catheter (95 cm STR) + 5F Select Catheter (120 cm SIM)
BMX7F95MBER120	7F BMX81 Delivery Catheter (95 cm MP) + 5F Select Catheter (120 cm BER)
BMX7F95MH1120	7F BMX81 Delivery Catheter (95 cm MP) + 5F Select Catheter (120 cm H1)
BMX7F95MSIM120	7F BMX81 Delivery Catheter (95 cm MP) + 5F Select Catheter (120 cm SIM)
BMX7F105BER130	7F BMX81 Delivery Catheter (105 cm STR) + 5F Select Catheter (130 cm BER)
BMX7F105H1130	7F BMX81 Delivery Catheter (105 cm STR) + 5F Select Catheter (130 cm H1)

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BMX7F105SIM130	7F BMX81 Delivery Catheter (105 cm STR) + 5F Select Catheter (130 cm SIM)
BMX7F105MBER130	7F BMX81 Delivery Catheter (105 cm MP) + 5F Select Catheter (130 cm BER)
BMX7F105MH1130	7F BMX81 Delivery Catheter (105 cm MP) + 5F Select Catheter (130 cm H1)
BMX7F105MSIM130	7F BMX81 Delivery Catheter (105 cm MP) + 5F Select Catheter (130 cm SIM)
BMX7F115BER130	7F BMX81 Delivery Catheter (115 cm STR) + 5F Select Catheter (130 cm BER)
BMX7F115H1130	7F BMX81 Delivery Catheter (115 cm STR) + 5F Select Catheter (130 cm H1)
BMX7F115SIM130	7F BMX81 Delivery Catheter (115 cm STR) + 5F Select Catheter (130 cm SIM)
BMX7F115MBER130	7F BMX81 Delivery Catheter (115 cm MP) + 5F Select Catheter (130 cm BER)
BMX7F115MH1130	7F BMX81 Delivery Catheter (115 cm MP) + 5F Select Catheter (130 cm H1)
BMX7F115MSIM130	7F BMX81 Delivery Catheter (115 cm MP) + 5F Select Catheter (130 cm SIM)
BMX9680BER105	8F BMX96 Delivery Catheter (80 cm STR) + 6F Select Catheter (105 cm BER)
BMX9690BER125	8F BMX96 Delivery Catheter (90 cm STR) + 6F Select Catheter (125 cm BER)
BMX9690SIM125	8F BMX96 Delivery Catheter (90 cm STR) + 6F Select Catheter (125 cm SIM)
BMX9690SIMV125	8F BMX96 Delivery Catheter (90 cm STR) + 6F Select Catheter (125 cm SIM-V)
BMX9690MBER125	8F BMX96 Delivery Catheter (90 cm MP) + 6F Select Catheter (125 cm BER)
BMX9690MSIM125	8F BMX96 Delivery Catheter (90 cm MP) + 6F Select Catheter (125 cm SIM)
BMX9690MSIMV125	8F BMX96 Delivery Catheter (90 cm MP) + 6F Select Catheter (125 cm SIM-V)
BMX96100BER125	8F BMX96 Delivery Catheter (100 cm STR) + 6F Select Catheter (125 cm BER)
BMX96100H1125	8F BMX96 Delivery Catheter (100 cm STR) + 6F Select Catheter (125 cm H1)
BMX96100SIM125	8F BMX96 Delivery Catheter (100 cm STR) + 6F Select Catheter (125 cm SIM)

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BMX96100SIMV125	8F BMX96 Delivery Catheter (100 cm STR) + 6F Select Catheter (125 cm SIM-V)
BMX96100MBER125	8F BMX96 Delivery Catheter (100 cm MP) + 6F Select Catheter (125 cm BER)
BMX96100MH1125	8F BMX96 Delivery Catheter (100 cm MP) + 6F Select Catheter (125 cm H1)
BMX96100MSIM125	8F BMX96 Delivery Catheter (100 cm MP) + 6F Select Catheter (125 cm SIM)
BMX96100MSIMV125	8F BMX96 Delivery Catheter (100 cm MP) + 6F Select Catheter (125 cm SIM-V)

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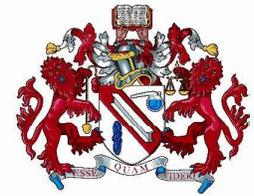
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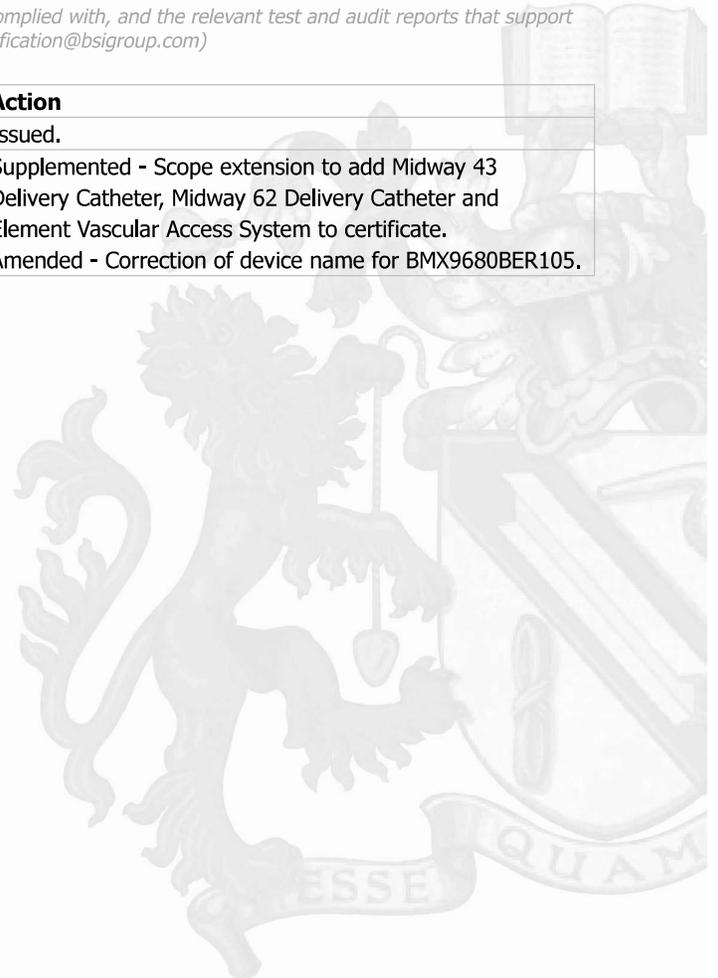
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### Certificate History

*(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
2024-05-29	3767975	Issued.
Current	30273390	Supplemented - Scope extension to add Midway 43 Delivery Catheter, Midway 62 Delivery Catheter and Element Vascular Access System to certificate. Amended - Correction of device name for BMX9680BER105.



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