

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

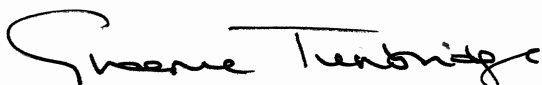
Address:

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):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-11-30**

Current Issue Date: **2024-09-03**

Starting Validity Date: **2024-09-03**

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.

Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Aspiration Catheters			
CAT3	Aspiration Catheter 3, Straight, 150cm	MDN 1202	081454801INDCAT5M
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		

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Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
CAT6STR115	Aspiration Catheter 6, Straight, 115cm	MDN 1202	081454801INDCAT5M
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		
CAT6MP40	Aspiration Catheter 6, MP, 40cm		
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		

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CAT8STR60	Aspiration Catheter 8, Straight, 60cm	MDN 1202	081454801INDCAT5M
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		
CAT8TORQ80	Aspiration Catheter 8, TORQ, 80cm		
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		

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Separators			
SEP3	Separator 3, 190cm	MDN 1203	081454801INDSEP89
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 + 110 Aspiration Tubing – KITS			
CAT3KIT	Aspiration Catheter 3, Straight, 150cm - KIT	MDN 1202	081454801INDKIT7M
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		

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Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
CAT6STR70KIT	Aspiration Catheter 6, Straight, 70cm - KIT	MDN 1202	081454801INDKIT7M
CAT6STR80KIT	Aspiration Catheter 6, Straight, 80cm - KIT		
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		

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CAT6MP132KIT	Aspiration Catheter 6, MP, 132cm - KIT	MDN 1202	081454801INDKIT7M
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		
CAT7XTORQ130KIT	Aspiration Catheter 7, XTORQ, 130cm - KIT		
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		

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CAT8STR115KIT	Aspiration Catheter 8, Straight, 115cm - KIT	MDN 1202	081454801INDKIT7M
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		
CATD50STR	Aspiration Catheter D, Straight, 50cm - KIT		
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		

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CATD	Aspiration Catheter D, MP, 50cm - KIT	MDN 1202	081454801INDKIT7M
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		

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CAT12XTORQ100KIT	Aspiration Catheter 12, XTORQ, 100cm - KIT	MDN 1202	081454801INDKIT7M
CAT12XTORQ110KIT	Aspiration Catheter 12, XTORQ, 110cm - KIT		
CAT12XTORQ115KIT	Aspiration Catheter 12, XTORQ, 115cm - KIT		
CAT12HTORQ30KIT	Aspiration Catheter 12, HTORQ, 30cm - KIT		
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		MDN 1202	081454801INDLITNGSL
LITNG7XTORQ130	Lightning 7, XTORQ, 130cm - KIT		
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		

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LITNG12HTORQ100	Lightning 12, HTORQ, 100cm - KIT	MDN 1202	081454801INDLITNGSL
LITNG12HTORQ115	Lightning 12, HTORQ, 115cm - KIT		
Lighting Flash (Flash Aspiration Catheter (CAT16) + Lightning Flash Aspiration Tubing) – KITs			
LITNGFST30H1	Flash Aspiration Catheter STR 30cm, Select H1 Tip, Lightning Flash Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGFST40H1	Flash Aspiration Catheter STR 40cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST50H1	Flash Aspiration Catheter STR 50cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST60H1	Flash Aspiration Catheter STR 60cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST70H1	Flash Aspiration Catheter STR 70cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST80H1	Flash Aspiration Catheter STR 80cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST85H1	Flash Aspiration Catheter STR 85cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST90H1	Flash Aspiration Catheter STR 90cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST95H1	Flash Aspiration Catheter STR 95cm, Select H1 Tip, Lightning Flash Tubing - KIT		

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LITNGFST100H1	Flash Aspiration Catheter STR 100cm, Select H1 Tip, Lightning Flash Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGFST110H1	Flash Aspiration Catheter STR 110cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST115H1	Flash Aspiration Catheter STR 115cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFST30BER	Flash Aspiration Catheter STR 30cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST40BER	Flash Aspiration Catheter STR 40cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST50BER	Flash Aspiration Catheter STR 50cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST60BER	Flash Aspiration Catheter STR 60cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST70BER	Flash Aspiration Catheter STR 70cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST80BER	Flash Aspiration Catheter STR 80cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST85BER	Flash Aspiration Catheter STR 85cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST90BER	Flash Aspiration Catheter STR 90cm, Select BER Tip, Lightning Flash Tubing - KIT		

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LITNGFST95BER	Flash Aspiration Catheter STR 95cm, Select BER Tip, Lightning Flash Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGFST100BER	Flash Aspiration Catheter STR 100cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST110BER	Flash Aspiration Catheter STR 110cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFST115BER	Flash Aspiration Catheter STR 115cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT30H1	Flash Aspiration Catheter XTORQ 30cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT40H1	Flash Aspiration Catheter XTORQ 40cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT50H1	Flash Aspiration Catheter XTORQ 50cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT60H1	Flash Aspiration Catheter XTORQ 60cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT70H1	Flash Aspiration Catheter XTORQ 70cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT80H1	Flash Aspiration Catheter XTORQ 80cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT85H1	Flash Aspiration Catheter XTORQ 85cm, Select H1 Tip, Lightning Flash Tubing - KIT		

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Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
LITNGFXT90H1	Flash Aspiration Catheter XTORQ 90cm, Select H1 Tip, Lightning Flash Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGFXT95H1	Flash Aspiration Catheter XTORQ 95cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT100H1	Flash Aspiration Catheter XTORQ 100cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT110H1	Flash Aspiration Catheter XTORQ 110cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT115H1	Flash Aspiration Catheter XTORQ 115cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT30BER	Flash Aspiration Catheter XTORQ 30cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT40BER	Flash Aspiration Catheter XTORQ 40cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT50BER	Flash Aspiration Catheter XTORQ 50cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT60BER	Flash Aspiration Catheter XTORQ 60cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT70BER	Flash Aspiration Catheter XTORQ 70cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT80BER	Flash Aspiration Catheter XTORQ 80cm, Select BER Tip, Lightning Flash Tubing - KIT		

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Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
LITNGFXT85BER	Flash Aspiration Catheter XTORQ 85cm, Select BER Tip, Lightning Flash Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGFXT90BER	Flash Aspiration Catheter XTORQ 90cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT95BER	Flash Aspiration Catheter XTORQ 95cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT100BER	Flash Aspiration Catheter XTORQ 100cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT110BER	Flash Aspiration Catheter XTORQ 110cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT115BER	Flash Aspiration Catheter XTORQ 115cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT30H1	Flash Aspiration Catheter HTORQ 30cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT40H1	Flash Aspiration Catheter HTORQ 40cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT50H1	Flash Aspiration Catheter HTORQ 50cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT60H1	Flash Aspiration Catheter HTORQ 60cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT70H1	Flash Aspiration Catheter HTORQ 70cm, Select H1 Tip, Lightning Flash Tubing - KIT		

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Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
LITNGFHT80H1	Flash Aspiration Catheter HTORQ 80cm, Select H1 Tip, Lightning Flash Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGFHT85H1	Flash Aspiration Catheter HTORQ 85cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT90H1	Flash Aspiration Catheter HTORQ 90cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT95H1	Flash Aspiration Catheter HTORQ 95cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT100H1	Flash Aspiration Catheter HTORQ 100cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT110H1	Flash Aspiration Catheter HTORQ 110cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT115H1	Flash Aspiration Catheter HTORQ 115cm, Select H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT30BER	Flash Aspiration Catheter HTORQ 30cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT40BER	Flash Aspiration Catheter HTORQ 40cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT50BER	Flash Aspiration Catheter HTORQ 50cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT60BER	Flash Aspiration Catheter HTORQ 60cm, Select BER Tip, Lightning Flash Tubing - KIT		

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Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
LITNGFHT70BER	Flash Aspiration Catheter HTORQ 70cm, Select BER Tip, Lightning Flash Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGFHT80BER	Flash Aspiration Catheter HTORQ 80cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT85BER	Flash Aspiration Catheter HTORQ 85cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT90BER	Flash Aspiration Catheter HTORQ 90cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT95BER	Flash Aspiration Catheter HTORQ 95cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT100BER	Flash Aspiration Catheter HTORQ 100cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT110BER	Flash Aspiration Catheter HTORQ 110cm, Select BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT115BER	Flash Aspiration Catheter HTORQ 115cm, Select BER Tip, Lightning Flash Tubing - KIT		

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Model	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Lightning Bolt 7 (Aspiration Catheter 7 + Lightning Bolt Aspiration Tubing) – KITs			
LITNGBT7STR130	Lightning Bolt 7 – Aspiration Catheter 7, Straight Tip, 130cm + Lightning Bolt Aspiration Tubing - KIT	MDN 1202	081454801INDLITNGSL
LITNGBT7TQ130	Lightning Bolt 7 – Aspiration Catheter 7, TORQ Tip, 130cm + Lightning Bolt Aspiration Tubing - KIT		
LITNGBT7XTQ130	Lightning Bolt 7 – Aspiration Catheter 7, XTORQ Tip, 130cm + Lightning Bolt Aspiration Tubing - 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
2021-11-30	3329040	Issued
Current	30001258	<p>Supplemented – Addition of kit configurations Lightning Flash and Lightning Bolt 7 to device schedule.</p> <p>Amended – Removal of system level Basic UDI-DI from device schedule header and include variant specific Basic UDI-DI in device schedule table. Update of primary device code for Aspiration Catheter + Lightning Aspiration Tubing – KITS</p>

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