



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

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 1 of 19

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





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

### MDR 739880 R000

#### **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	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
<b>Aspiration Cathet</b>	ers		A WELL
CAT3	Aspiration Catheter 3, Straight, 150cm	MDN 1202	081454801INDCAT5M
CAT5L125	Aspiration Catheter 5, Straight, 125cm		
CAT5L127	Aspiration Catheter 5, Straight, 127cm	-	2/10/00
CAT5	Aspiration Catheter 5, Straight, 132cm		
CAT5MP125	Aspiration Catheter 5, MP, 125cm	-U (7)355	
CAT5MP127	Aspiration Catheter 5, MP, 127cm	7 2 11	
CAT6STR30	Aspiration Catheter 6, Straight, 30cm		
CAT6STR40	Aspiration Catheter 6, Straight, 40cm	54// //	
CAT6STR50	Aspiration Catheter 6, Straight, 50cm		do bal
CAT6STR60	Aspiration Catheter 6, Straight, 60cm	SIV ARRE	
CAT6STR70	Aspiration Catheter 6, Straight, 70cm	T //tela	Ma Val
CAT6STR80	Aspiration Catheter 6, Straight, 80cm		
CAT6STR90	Aspiration Catheter 6, Straight, 90cm		The state of
CAT6STR100	Aspiration Catheter 6, Straight, 100cm		1000
CAT6STR110	Aspiration Catheter 6, Straight, 110cm	7 29/10	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 2 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (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		AT DESCRIPTION
CAT6MP30	Aspiration Catheter 6, MP, 30cm		A AMERICAN
CAT6MP40	Aspiration Catheter 6, MP, 40cm	106-	AL TAPE
CAT6MP50	Aspiration Catheter 6, MP, 50cm	50000	an Mary
CAT6MP60	Aspiration Catheter 6, MP, 60cm		3 AS G.
CAT6MP70	Aspiration Catheter 6, MP, 70cm		
CAT6MP80	Aspiration Catheter 6, MP, 80cm		
CAT6MP90	Aspiration Catheter 6, MP, 90cm	S A '900	
CAT6MP100	Aspiration Catheter 6, MP, 100cm		
CAT6MP110	Aspiration Catheter 6, MP, 110cm		
CAT6MP115	Aspiration Catheter 6, MP, 115cm	SM AND	(000)
CAT6MP120	Aspiration Catheter 6, MP, 120cm	N / Alle	34
CAT6MP125	Aspiration Catheter 6, MP, 125cm	N ASSESSE	
CAT6MP132	Aspiration Catheter 6, MP, 132cm		
CAT6MP135	Aspiration Catheter 6, MP, 135cm		
CAT8STR30	Aspiration Catheter 8, Straight, 30cm	4 9	2662
CAT8STR40	Aspiration Catheter 8, Straight, 40cm	Jan San	
CAT8STR50	Aspiration Catheter 8, Straight, 50cm	Make	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 3 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
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	6	
CAT8STR90	Aspiration Catheter 8, Straight, 90cm		
CAT8STR95	Aspiration Catheter 8, Straight, 95cm		O AMERICA
CAT8STR100	Aspiration Catheter 8, Straight, 100cm	366	AR WARE
CAT8STR110	Aspiration Catheter 8, Straight, 110cm		A. Mr.
CAT8STR115	Aspiration Catheter 8, Straight, 115cm		2000
CAT8TORQ30	Aspiration Catheter 8, TORQ, 30cm		
CAT8TORQ40	Aspiration Catheter 8, TORQ, 40cm		
CAT8TORQ50	Aspiration Catheter 8, TORQ, 50cm	190	
CAT8TORQ60	Aspiration Catheter 8, TORQ, 60cm		
CAT8TORQ70	Aspiration Catheter 8, TORQ, 70cm		
CAT8TORQ80	Aspiration Catheter 8, TORQ, 80cm		COLUMN /
CAT8TORQ85	Aspiration Catheter 8, TORQ, 85cm	V Alles	3-97
CAT8TORQ95	Aspiration Catheter 8, TORQ, 95cm	/ /A	
CAT8TORQ110	Aspiration Catheter 8, TORQ, 110cm	// 100	
CAT8XTORQ90	Aspiration Catheter 8, XTORQ, 90cm	7 101	A STATE OF THE STA
CAT8XTORQ100	Aspiration Catheter 8, XTORQ, 100cm	917	1862
CAT8XTORQ115	Aspiration Catheter 8, XTORQ, 115cm	Jan San San San San San San San San San S	

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

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Starting Validity Date: 2024-09-03

Page 4 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Separators			10
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	106-	ALC WAS TO
SEP8	Separator 8, 150cm		TO ME
SEPD	Separator D, 90cm		500 G
SEP12	Separator 12, 150cm		
SEP1250	Separator 12, 90cm		
Aspiration Cathete	er + 110 Aspiration Tubing - KITs	A 900	
CAT3KIT	Aspiration Catheter 3, Straight, 150cm - KIT	MDN 1202	081454801INDKIT7M
CAT5L125KIT	Aspiration Catheter 5, Straight, 125cm - KIT		
CAT5L127KIT	Aspiration Catheter 5, Straight, 127cm - KIT	M AND	6000
CAT5KIT	Aspiration Catheter 5, Straight, 132cm - KIT	A A A A A A A A A A A A A A A A A A A	277
CAT5MP125KIT	Aspiration Catheter 5, MP, 125cm - KIT	7 <i>(A</i> )	
CAT5MP127KIT	Aspiration Catheter 5, MP, 127cm - KIT		
CAT6STR30KIT	Aspiration Catheter 6, Straight, 30cm - KIT		
CAT6STR40KIT	Aspiration Catheter 6, Straight, 40cm - KIT		11 6582
CAT6STR50KIT	Aspiration Catheter 6, Straight, 50cm - KIT		17.
CAT6STR60KIT	Aspiration Catheter 6, Straight, 60cm - KIT	MARKA	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 5 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (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		. 19
CAT6STR90KIT	Aspiration Catheter 6, Straight, 90cm - KIT		A . 4
CAT6STR100KIT	Aspiration Catheter 6, Straight, 100cm - KIT		
CAT6STR110KIT	Aspiration Catheter 6, Straight, 110cm - KIT		
CAT6STR115KIT	Aspiration Catheter 6, Straight, 115cm - KIT	3300	TO ARE COM
CAT6STR120KIT	Aspiration Catheter 6, Straight, 120cm - KIT	100	
CAT6STR125KIT	Aspiration Catheter 6, Straight, 125cm - KIT		TO MEST
CAT6STR132KIT	Aspiration Catheter 6, Straight, 132cm - KIT		500
CAT6KIT	Aspiration Catheter 6, Straight, 135cm - KIT		
CAT6MP30KIT	Aspiration Catheter 6, MP, 30cm - KIT		
CAT6MP40KIT	Aspiration Catheter 6, MP, 40cm - KIT	3 (90)	
CAT6MP50KIT	Aspiration Catheter 6, MP, 50cm - KIT		
CAT6MP60KIT	Aspiration Catheter 6, MP, 60cm - KIT		
CAT6MP70KIT	Aspiration Catheter 6, MP, 70cm - KIT	N/ AND	COMPANY STATE
CAT6MP80KIT	Aspiration Catheter 6, MP, 80cm - KIT	T AND T	377
CAT6MP90KIT	Aspiration Catheter 6, MP, 90cm - KIT	7 //	
CAT6MP100KIT	Aspiration Catheter 6, MP, 100cm - KIT	11 1000	
CAT6MP110KIT	Aspiration Catheter 6, MP, 110cm - KIT		1
CAT6MP115KIT	Aspiration Catheter 6, MP, 115cm - KIT	// SII	2602 11
CAT6MP120KIT	Aspiration Catheter 6, MP, 120cm - KIT	Same	
CAT6MP125KIT	Aspiration Catheter 6, MP, 125cm - KIT	JAHA	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 6 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
CAT6MP132KIT	Aspiration Catheter 6, MP, 132cm - KIT	MDN 1202	081454801INDKIT7M
CAT6MP135KIT	Aspiration Catheter 6, MP, 135cm - KIT		
CAT7STR50KIT	Aspiration Catheter 7, Straight, 50cm - KIT		A . 4
CAT7STR130KIT	Aspiration Catheter 7, Straight, 130cm - KIT		
CAT7STR160KIT	Aspiration Catheter 7, Straight, 160cm - KIT		
CAT7TORQ50KIT	Aspiration Catheter 7, TORQ, 50cm - KIT	- B33	
CAT7TORQ130KIT	Aspiration Catheter 7, TORQ, 130cm - KIT	100	
CAT7TORQ160KIT	Aspiration Catheter 7, TORQ, 160cm - KIT		OF WEST
CAT7DKIT	Aspiration Catheter 7D, XTORQ, 50cm - KIT		300 Gra
CAT7XTORQ130KIT	Aspiration Catheter 7, XTORQ, 130cm - KIT		
CAT7XTORQ160KIT	Aspiration Catheter 7, XTORQ, 160cm - KIT		
CAT8STR30KIT	Aspiration Catheter 8, Straight, 30cm - KIT	DR 45	
CAT8STR40KIT	Aspiration Catheter 8, Straight, 40cm - KIT		
CAT8STR50KIT	Aspiration Catheter 8, Straight, 50cm - KIT		
CAT8STR60KIT	Aspiration Catheter 8, Straight, 60cm - KIT	M ASS	adday 1
CAT8STR70KIT	Aspiration Catheter 8, Straight, 70cm - KIT	A A STATE OF	377
CAT8STR80KIT	Aspiration Catheter 8, Straight, 80cm - KIT	7 //	
CAT8STR85KIT	Aspiration Catheter 8, Straight, 85cm - KIT	// 1000	
CAT8STR90KIT	Aspiration Catheter 8, Straight, 90cm - KIT		
CAT8STR95KIT	Aspiration Catheter 8, Straight, 95cm - KIT	74 9117	2862
CAT8STR100KIT	Aspiration Catheter 8, Straight, 100cm - KIT	Jan Jan	
CAT8STR110KIT	Aspiration Catheter 8, Straight, 110cm - KIT	MARA	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 7 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
CAT8STR115KIT	Aspiration Catheter 8, Straight, 115cm - KIT	MDN 1202	081454801INDKIT7M
CAT8TORQ30KIT	Aspiration Catheter 8, TORQ, 30cm - KIT		
CAT8TORQ40KIT	Aspiration Catheter 8, TORQ, 40cm - KIT		A . 4
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	166-	45 84 3
CAT8TORQ85KIT	Aspiration Catheter 8, TORQ, 85cm - KIT		TO WEST
CAT8TORQ95KIT	Aspiration Catheter 8, TORQ, 95cm - KIT		300 Gra
CAT8TORQ110KIT	Aspiration Catheter 8, TORQ, 110cm - KIT		
CAT8XTORQ90KIT	Aspiration Catheter 8, XTORQ, 90cm - KIT		
CAT8XTORQ100KIT	Aspiration Catheter 8, XTORQ, 100cm - KIT	300	
CAT8XTORQ115KIT	Aspiration Catheter 8, XTORQ, 115cm - KIT		
CATD30STR	Aspiration Catheter D, Straight, 30cm - KIT		
CATD35STR	Aspiration Catheter D, Straight, 35cm - KIT	M AND	Cald and I
CATD40STR	Aspiration Catheter D, Straight, 40cm - KIT	N ANNE	377
CATD45STR	Aspiration Catheter D, Straight, 45cm - KIT	7 //	
CATD50STR	Aspiration Catheter D, Straight, 50cm - KIT	// 1650	
CATD30	Aspiration Catheter D, MP, 30cm - KIT		
CATD35	Aspiration Catheter D, MP, 35cm - KIT		2862
CATD40	Aspiration Catheter D, MP, 40cm - KIT	S San	
CATD45	Aspiration Catheter D, MP, 45cm - KIT	MARA	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 8 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
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	100	AR WAS S
CAT12STR85KIT	Aspiration Catheter 12, Straight, 85cm - KIT		an Miran
CAT12STR90KIT	Aspiration Catheter 12, Straight, 90cm - KIT	700000	300 Ge
CAT12STR95KIT	Aspiration Catheter 12, Straight, 95cm - KIT		
CAT12STR100KIT	Aspiration Catheter 12, Straight, 100cm - KIT		
CAT12STR110KIT	Aspiration Catheter 12, Straight, 110cm - KIT	1900	
CAT12STR115KIT	Aspiration Catheter 12, Straight, 115cm - KIT		
CAT12XTORQ30KIT	Aspiration Catheter 12, XTORQ, 30cm - KIT		
CAT12XTORQ40KIT	Aspiration Catheter 12, XTORQ, 40cm - KIT	M A	COMP I
CAT12XTORQ50KIT	Aspiration Catheter 12, XTORQ, 50cm - KIT	T AND	3-77
CAT12XTORQ60KIT	Aspiration Catheter 12, XTORQ, 60cm - KIT	7 //	
CAT12XTORQ70KIT	Aspiration Catheter 12, XTORQ, 70cm - KIT	// 100	
CAT12XTORQ80KIT	Aspiration Catheter 12, XTORQ, 80cm - KIT		
CAT12XTORQ85KIT	Aspiration Catheter 12, XTORQ, 85cm - KIT	4 917	1862
CAT12XTORQ90KIT	Aspiration Catheter 12, XTORQ, 90cm - KIT	S Jan	
CAT12XTORQ95KIT	Aspiration Catheter 12, XTORQ, 95cm - KIT	MARA	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 9 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
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		Y AMERICAN
CAT12HTORQ60KIT	Aspiration Catheter 12, HTORQ, 60cm - KIT	100	45 10 2 3
CAT12HTORQ70KIT	Aspiration Catheter 12, HTORQ, 70cm - KIT		OF THE STATE OF
CAT12HTORQ80KIT	Aspiration Catheter 12, HTORQ, 80cm - KIT		3 AS (G)
CAT12HTORQ85KIT	Aspiration Catheter 12, HTORQ, 85cm - KIT		
CAT12HTORQ90KIT	Aspiration Catheter 12, HTORQ, 90cm - KIT		
CAT12HTORQ95KIT	Aspiration Catheter 12, HTORQ, 95cm - KIT	1900	
CAT12HTORQ100KIT	Aspiration Catheter 12, HTORQ, 100cm - KIT		
CAT12HTORQ110KIT	Aspiration Catheter 12, HTORQ, 110cm - KIT	1 // //	
CAT12HTORQ115KIT	Aspiration Catheter 12, HTORQ, 115cm - KIT	M Ass	CONTRACTOR
Aspiration Catheter +	- Lightning Aspiration Tubing — KITs	y Anna	30
LITNG7XTORQ130	Lightning 7, XTORQ, 130cm - KIT	MDN 1202	081454801INDLITNGSL
LITNG8STR85	Lightning 8, Straight, 85cm - KIT	// Wall	
LITNG8TORQ85	Lightning 8, TORQ, 85cm - KIT	7 )	
LITNG8XTORQ115	Lightning 8, XTORQ, 115cm - KIT		11 6532
LITNG12XTORQ100	Lightning 12, XTORQ, 100cm - KIT	Jana	
LITNG12XTORQ115	Lightning 12, XTORQ, 115cm - KIT	MARA	

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 10 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
LITNG12HTORQ100	Lightning 12, HTORQ, 100cm - KIT	MDN 1202	081454801INDLITNGSL
LITNG12HTORQ115	Lightning 12, HTORQ, 115cm - KIT		. 11
Lighting Flash (Flash	Aspiration Catheter (CAT16) + Lightning Fla	ash Aspiration T	ubing) – 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		A COST
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	190	
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	V AN	444 30
LITNGFST90H1	Flash Aspiration Catheter STR 90cm, Select H1 Tip, Lightning Flash Tubing - KIT		041
LITNGFST95H1	Flash Aspiration Catheter STR 95cm, Select H1 Tip, Lightning Flash Tubing - KIT		400-71

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 11 of 19

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.





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

### MDR 739880 R000

Model	Device Name	Type (Codes as	Variant Basic UDI-DI
		per (EU)	1
		2017/2185)	
LITNGFST100H1	Flash Aspiration Catheter STR 100cm, Select H1	MDN 1202	081454801INDLITNGSL
	Tip, Lightning Flash Tubing - KIT		Α. Μ
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		A WELLINE
LITNGFST30BER	Flash Aspiration Catheter STR 30cm, Select BER	2006	AB WAS ST
	Tip, Lightning Flash Tubing - KIT	5-75 1119	OF MESSE
LITNGFST40BER	Flash Aspiration Catheter STR 40cm, Select BER		5000
	Tip, Lightning Flash Tubing - KIT		
LITNGFST50BER	Flash Aspiration Catheter STR 50cm, Select BER		
	Tip, Lightning Flash Tubing - KIT	V (4)	
LITNGFST60BER	Flash Aspiration Catheter STR 60cm, Select BER		
	Tip, Lightning Flash Tubing - KIT	71 603	
LITNGFST70BER	Flash Aspiration Catheter STR 70cm, Select BER	// //	1000000
	Tip, Lightning Flash Tubing - KIT	W AND	4 2 M
LITNGFST80BER	Flash Aspiration Catheter STR 80cm, Select BER	ASS	127 1
	Tip, Lightning Flash Tubing - KIT		
LITNGFST85BER	Flash Aspiration Catheter STR 85cm, Select BER	11 1000	
	Tip, Lightning Flash Tubing - KIT		
LITNGFST90BER	Flash Aspiration Catheter STR 90cm, Select BER		2002
	Tip, Lightning Flash Tubing - KIT	D	44,

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 12 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (Codes as per (EU)	Variant Basic UDI-DI
		2017/2185)	
LITNGFST95BER	Flash Aspiration Catheter STR 95cm, Select BER	· -	081454801INDLITNGSL
	Tip, Lightning Flash Tubing - KIT		
LITNGFST100BER	Flash Aspiration Catheter STR 100cm, Select		
	BER Tip, Lightning Flash Tubing - KIT		
LITNGFST110BER	Flash Aspiration Catheter STR 110cm, Select		A March (
	BER Tip, Lightning Flash Tubing - KIT		A WELL
LITNGFST115BER	Flash Aspiration Catheter STR 115cm, Select	106	AB WAS ST
	BER Tip, Lightning Flash Tubing - KIT	F13.519	OF MESSE
LITNGFXT30H1	Flash Aspiration Catheter XTORQ 30cm, Select		5000
	H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT40H1	Flash Aspiration Catheter XTORQ 40cm, Select		(Sec. )
	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	// //	100000
	H1 Tip, Lightning Flash Tubing - KIT	W AND	45, 90
LITNGFXT70H1	Flash Aspiration Catheter XTORQ 70cm, Select	ASSE	- 1-7 A
	H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT80H1	Flash Aspiration Catheter XTORQ 80cm, Select	11 100	
	H1 Tip, Lightning Flash Tubing - KIT	7 )	The second
LITNGFXT85H1	Flash Aspiration Catheter XTORQ 85cm, Select	C C	2662
	H1 Tip, Lightning Flash Tubing - KIT		17.

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 13 of 19

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





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

### MDR 739880 R000

Model	Device Name	Type (Codes as	Variant Basic UDI-DI
		per (EU)	1
		2017/2185)	
LITNGFXT90H1	Flash Aspiration Catheter XTORQ 90cm, Select	MDN 1202	081454801INDLITNGSL
	H1 Tip, Lightning Flash Tubing - KIT		Α. Μ
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		A WELLINE
LITNGFXT110H1	Flash Aspiration Catheter XTORQ 110cm, Select	106-	AR WAS SE
	H1 Tip, Lightning Flash Tubing - KIT	5-75/19	OF MESSE
LITNGFXT115H1	Flash Aspiration Catheter XTORQ 115cm, Select		500
	H1 Tip, Lightning Flash Tubing - KIT		
LITNGFXT30BER	Flash Aspiration Catheter XTORQ 30cm, Select		(9.50)
	BER Tip, Lightning Flash Tubing - KIT	Y GR	
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	M ASS	1 2 2 1 1 1 1
LITNGFXT60BER	Flash Aspiration Catheter XTORQ 60cm, Select	ASS	127 0
	BER Tip, Lightning Flash Tubing - KIT	/A	
LITNGFXT70BER	Flash Aspiration Catheter XTORQ 70cm, Select	11 1000	
	BER Tip, Lightning Flash Tubing - KIT		
LITNGFXT80BER	Flash Aspiration Catheter XTORQ 80cm, Select	Can	262
	BER Tip, Lightning Flash Tubing - KIT	D	44,

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 14 of 19

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.





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

### MDR 739880 R000

Model	Device Name	<b>Type</b> (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		SPA]
LITNGFXT95BER	Flash Aspiration Catheter XTORQ 95cm, Select BER Tip, Lightning Flash Tubing - KIT	900	The second
LITNGFXT100BER	Flash Aspiration Catheter XTORQ 100cm, Select BER Tip, Lightning Flash Tubing - KIT	3696	A DEED
LITNGFXT110BER	Flash Aspiration Catheter XTORQ 110cm, Select BER Tip, Lightning Flash Tubing - KIT		200
LITNGFXT115BER	Flash Aspiration Catheter XTORQ 115cm, Select BER Tip, Lightning Flash Tubing - KIT	300	
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	V AS	(200) /
LITNGFHT50H1	Flash Aspiration Catheter HTORQ 50cm, Select H1 Tip, Lightning Flash Tubing - KIT	ASS	DOLA
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	5.8	1862

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 15 of 19

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.





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

### MDR 739880 R000

Model	Device Name	1	Variant Basic UDI-DI
		per (EU)	1
		2017/2185)	
LITNGFHT80H1	Flash Aspiration Catheter HTORQ 80cm, Select	MDN 1202	081454801INDLITNGSL
	H1 Tip, Lightning Flash Tubing - KIT		A. U
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		A WELLINE
LITNGFHT95H1	Flash Aspiration Catheter HTORQ 95cm, Select	2006	AL WAS SET
	H1 Tip, Lightning Flash Tubing - KIT	5-73/11/19	OF MESSE
LITNGFHT100H1	Flash Aspiration Catheter HTORQ 100cm, Select		500
	H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT110H1	Flash Aspiration Catheter HTORQ 110cm, Select		(9.50)
	H1 Tip, Lightning Flash Tubing - KIT	V (41)	
LITNGFHT115H1	Flash Aspiration Catheter HTORQ 115cm, Select		
	H1 Tip, Lightning Flash Tubing - KIT		
LITNGFHT30BER	Flash Aspiration Catheter HTORQ 30cm, Select	M ASS	
	BER Tip, Lightning Flash Tubing - KIT	II ASSI	1 2 2 1 1 1 1
LITNGFHT40BER	Flash Aspiration Catheter HTORQ 40cm, Select	ASSE	127 0
	BER Tip, Lightning Flash Tubing - KIT	/Attended	
LITNGFHT50BER	Flash Aspiration Catheter HTORQ 50cm, Select	11 100	
	BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT60BER	Flash Aspiration Catheter HTORQ 60cm, Select	Can	2002
	BER Tip, Lightning Flash Tubing - KIT		44,

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 16 of 19

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.





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

### MDR 739880 R000

Model	Device Name	Type (Codes as	Variant Basic UDI-DI
		per (EU)	1
		2017/2185)	
LITNGFHT70BER	Flash Aspiration Catheter HTORQ 70cm, Select	MDN 1202	081454801INDLITNGSL
	BER Tip, Lightning Flash Tubing - KIT		Α. Μ
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		A WELLINE
LITNGFHT90BER	Flash Aspiration Catheter HTORQ 90cm, Select	2006	AB WAS SO
	BER Tip, Lightning Flash Tubing - KIT	573.55	OF MEST
LITNGFHT95BER	Flash Aspiration Catheter HTORQ 95cm, Select		500
	BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT100BER	Flash Aspiration Catheter HTORQ 100cm, Select		(Sec. )
	BER Tip, Lightning Flash Tubing - KIT	Y (GR	
LITNGFHT110BER	Flash Aspiration Catheter HTORQ 110cm, Select		
	BER Tip, Lightning Flash Tubing - KIT		
LITNGFHT115BER	Flash Aspiration Catheter HTORQ 115cm, Select	// //	16 20 0000 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
	BER Tip, Lightning Flash Tubing - KIT	M ASSIV	22,20

First Issue Date: 2021-11-30 Starting Validity Date: 2024-09-03

Current Issue Date: **2024-09-03** Expiry Date: **2026-11-29** 

...making excellence a habit."

Page 17 of 19

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.





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

### MDR 739880 R000

Model	Device Name	Type (Codes as	Variant Basic UDI-DI
		per (EU)	
		2017/2185)	
Lightning Bolt 7 (As	spiration Catheter 7 + Lightning Bolt Aspiratio	n Tubing) – KIT	s
LITNGBT7STR130	Lightning Bolt 7 – Aspiration Catheter 7,	MDN 1202	081454801INDLITNGSL
	Straight Tip, 130cm + Lightning Bolt Aspiration		
	Tubing - KIT		
LITNGBT7TQ130	Lightning Bolt 7 – Aspiration Catheter 7, TORQ		
	Tip, 130cm + Lightning Bolt Aspiration Tubing -		
	KIT	2000	All Was So
LITNGBT7XTQ130	Lightning Bolt 7 – Aspiration Catheter 7, XTORQ		TO WEST
	Tip, 130cm + Lightning Bolt Aspiration Tubing -	7	5 6 76 7
	KIT		

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

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

Starting Validity Date: 2024-09-03

Expiry Date: 2026-11-29

...making excellence a habit.™

Page 18 of 19

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.





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

### MDR 739880 R000

#### **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	Supplemented – Addition of kit configurations Lightning Flash and Lightning Bolt 7 to device schedule.
		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

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

Current Issue Date: 2024-09-03

Starting Validity Date: 2024-09-03

Expiry Date: 2026-11-29

...making excellence a habit.™

Page 19 of 19

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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.