



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

MDR 763182 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: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 1 of 11

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 763182 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

The Penumbra System is designed to remove thrombus and restore blood flow in the neurovasculature using aspiration.

Risk Classification: Class III

Catalogue Number	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Reperfusion Cathete	ers	D ASLA	
PSC041	Reperfusion Catheter 041, 137 cm	ARV	A Commence
3MAXC	Reperfusion Catheter 3MAX, 160 cm	48"	
4MAXC125	Reperfusion Catheter 4MAX, 125 cm		
4MAXC130	Reperfusion Catheter 4MAX, 130 cm		CO.
4MAXC	Reperfusion Catheter 4MAX, 139 cm		
PSC054L125	Reperfusion Catheter 5MAX, 125 cm		
PSC054L127	Reperfusion Catheter 5MAX, 127 cm		
PSC054	Reperfusion Catheter 5MAX, 132 cm		
5MAXJETDL135	Reperfusion Catheter Penumbra JET D, 135 cm		
5MAXJETDL136	Reperfusion Catheter Penumbra JET D, 136 cm	MDN 1202 081454801PSCA	0014E4901DCCAT04
5MAXJETDL137	Reperfusion Catheter Penumbra JET D, 137 cm		001434001F3CA194
5MAXJETD	Reperfusion Catheter Penumbra JET D, 138 cm	7 7 1	
5MAXJETDL139	Reperfusion Catheter Penumbra JET D, 139 cm		
5MAXACE125	Reperfusion Catheter ACE 60, 125 cm		
5MAXACE127	Reperfusion Catheter ACE 60, 127 cm		
5MAXACE132	Reperfusion Catheter ACE 60, 132 cm		THE PROPERTY OF
5MAXACE064L115	Reperfusion Catheter ACE 64, 115 cm	400000	
5MAXACE064L120	Reperfusion Catheter ACE 64, 120 cm		
5MAXACE064L125	Reperfusion Catheter ACE 64, 125 cm		
5MAXACE064L127	Reperfusion Catheter ACE 64, 127 cm		MINA

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 2 of 11

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 763182 R000

Catalogue Number	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Reperfusion Cathete	rs	·	
5MAXACE064	Reperfusion Catheter ACE 64, 132 cm		
5MAXACE068L115	Reperfusion Catheter ACE 68, 115 cm		17/650
5MAXACE068L120	Reperfusion Catheter ACE 68, 120 cm	A	A 100
5MAXACE068L125	Reperfusion Catheter ACE 68, 125 cm		177
5MAXACE068L127	Reperfusion Catheter ACE 68, 127 cm		
5MAXACE068	Reperfusion Catheter ACE 68, 132 cm		
RED43115	Reperfusion Catheter RED 43, 115 cm	AR W	
RED43120	Reperfusion Catheter RED 43, 120 cm	ANTINA - STORY	
RED43125	Reperfusion Catheter RED 43, 125 cm	THE REAL PROPERTY.	
RED43127	Reperfusion Catheter RED 43, 127 cm		Call &
RED43132	Reperfusion Catheter RED 43, 132 cm		
RED43136	Reperfusion Catheter RED 43, 136 cm	7/5/19/20 19/20	
RED43138	Reperfusion Catheter RED 43, 138 cm	Year and the second	
RED43145	Reperfusion Catheter RED 43, 145 cm	MDN 1202	001 4F 4001 DCCATO4
RED43150	Reperfusion Catheter RED 43, 150 cm	MDN 1202	081454801PSCAT94
RED43153	Reperfusion Catheter RED 43, 153 cm		
RED43155	Reperfusion Catheter RED 43, 155 cm	7 ASSTRUCTION	
RED43160	Reperfusion Catheter RED 43, 160 cm	2 2 2	
RED43	Reperfusion Catheter RED 43, 162 cm	1	
RED43167	Reperfusion Catheter RED 43, 167 cm		
RED62115	Reperfusion Catheter RED 62, 115 cm		
RED62120	Reperfusion Catheter RED 62, 120 cm		I A WA
RED62125	Reperfusion Catheter RED 62, 125 cm	1000	
RED62132	Reperfusion Catheter RED 62, 132 cm		
RED62S	Reperfusion Catheter RED 62, 138 cm	2990	
RED62145	Reperfusion Catheter RED 62, 145 cm		
RED62150	Reperfusion Catheter RED 62, 150 cm		A STATE
RED62155	Reperfusion Catheter RED 62, 155 cm	CALL ESSI	

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 3 of 11

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 763182 R000

Catalogue Number	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Reperfusion Catheter	s		
RED62L	Reperfusion Catheter RED 62, 160 cm		
RED68L115	Reperfusion Catheter RED 68, 115 cm		7.69
RED68L120	Reperfusion Catheter RED 68, 120 cm	1	
RED68L125	Reperfusion Catheter RED 68, 125 cm		177
RED68L127	Reperfusion Catheter RED 68, 127 cm		
RED68	Reperfusion Catheter RED 68, 132 cm	y MA	
5MAXJET7L115	Reperfusion Catheter Penumbra JET 7 Standard Tip, 115 cm	ARW	A COLUMN TO A COLU
5MAXJET7L120	Reperfusion Catheter Penumbra JET 7 Standard Tip, 120 cm	MA SERVE	
5MAXJET7L125	Reperfusion Catheter Penumbra JET 7 Standard Tip, 125 cm		
5MAXJET7L127	Reperfusion Catheter Penumbra JET 7 Standard Tip, 127 cm		(30)
5MAXJET7	Reperfusion Catheter Penumbra JET 7 Standard Tip, 132 cm	Reperfusion Catheter Penumbra JET 7 Standard Tip, 132 cm MDN 1202	
RED72L115	Reperfusion Catheter RED 72, 115 cm		081454801PSCAT94
RED72L120	Reperfusion Catheter RED 72, 120 cm		
RED72L125	Reperfusion Catheter RED 72, 125 cm		
RED72L127	Reperfusion Catheter RED 72, 127 cm		
RED72	Reperfusion Catheter RED 72, 132 cm		
RED78115	Reperfusion Catheter RED 78, 115 cm	A COM	
RED78120	Reperfusion Catheter RED 78, 120 cm	D. P.	
RED78125	Reperfusion Catheter RED 78, 125 cm		
RED78127	Reperfusion Catheter RED 78, 127 cm		
RED78	Reperfusion Catheter RED 78, 132 cm		
RED78138	Reperfusion Catheter RED 78, 138 cm		I A A

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 4 of 11

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 763182 R000

Catalogue Number	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Separators			
PSS041	Separator 041		Lacre
3MAXS	Separator 3MAX	MDN 1203	0014540010005000
PSF041	Separator 4MAX	MDN 1203	081454801PSSEPBQ
PSF054	Separator 5MAX		177
3D Revascularization	Device	CR ADD	A CALL
PSR3D	3D Revascularization Device	MDN 1203	081454801PSR3D98
Reperfusion Catheter	+ Aspiration Tubing - KITs	AR W	A Francisco
3MAXCKIT	Reperfusion Catheter 3MAX, 160 cm and Hi-Flow Aspiration Tubing - KIT	- 60	
3MAXCMKIT	Reperfusion Catheter 3MAX, 160 cm and Aspiration Tubing - KIT		
4MAXC125KIT	Reperfusion Catheter 4MAX, 125 cm and Hi-Flow Aspiration Tubing - KIT		
4MAXC125MKIT	Reperfusion Catheter 4MAX, 125 cm and Aspiration Tubing - KIT		
4MAXC130KIT	Reperfusion Catheter 4MAX, 130 cm and Hi-Flow Aspiration Tubing - KIT		
4MAXC130MKIT	Reperfusion Catheter 4MAX, 130 cm and Aspiration Tubing - KIT		
4MAXCKIT	Reperfusion Catheter 4MAX, 139 cm and Hi-Flow Aspiration Tubing - KIT		
4MAXCMKIT	Reperfusion Catheter 4MAX, 139 cm and Aspiration Tubing - KIT		
PSC054L125KIT	Reperfusion Catheter 5MAX, 125 cm and Hi-Flow Aspiration Tubing - KIT		
PSC054L125MKIT	Reperfusion Catheter 5MAX, 125 cm and Aspiration Tubing - KIT	7 MDN 1202	004 45 4004 BGWTED
PSC054L127KIT	Reperfusion Catheter 5MAX, 127 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
PSC054L127MKIT	Reperfusion Catheter 5MAX, 127 cm and Aspiration Tubing - KIT	- L'	
PSC054KIT	Reperfusion Catheter 5MAX, 132 cm and Hi-Flow Aspiration Tubing - KIT		
PSC054MKIT	Reperfusion Catheter 5MAX, 132 cm and Aspiration Tubing - KIT		
5MAXJETDL135KIT	Reperfusion Catheter Penumbra JET D, 135 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXJETDL135MKIT	Reperfusion Catheter Penumbra JET D, 135 cm and Aspiration Tubing - KIT	100	
5MAXJETDL136KIT	Reperfusion Catheter Penumbra JET D, 136 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXJETDL136MKIT	Reperfusion Catheter Penumbra JET D, 136 cm and Aspiration Tubing - KIT		Jan Sel YV

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 5 of 11

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 763182 R000

Catalogue Number	Device Name		Variant Basic UDI-DI
Reperfusion Catheter	+ Aspiration Tubing - KITs		
5MAXJETDL137KIT	Reperfusion Catheter Penumbra JET D, 137 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXJETDL137MKIT	Reperfusion Catheter Penumbra JET D, 137 cm and Aspiration Tubing - KIT		
5MAXJETDKIT	Reperfusion Catheter Penumbra JET D, 138 cm and Hi-Flow Aspiration Tubing - KIT	3 7	A STE
5MAXJETDMKIT	Reperfusion Catheter Penumbra JET D, 138 cm and Aspiration Tubing - KIT		
5MAXJETDL139KIT	Reperfusion Catheter Penumbra JET D, 139 cm and Hi-Flow Aspiration Tubing - KIT	454	100000
5MAXJETDL139MKIT	Reperfusion Catheter Penumbra JET D, 139 cm and Aspiration Tubing - KIT		
5MAXACE125KIT	Reperfusion Catheter ACE 60, 125 cm and Hi-Flow Aspiration Tubing - KIT	PAIN	(50)
5MAXACE125MKIT	Reperfusion Catheter ACE 60, 125 cm and Aspiration Tubing - KIT		081454801PSKITB
5MAXACE127KIT	Reperfusion Catheter ACE 60, 127 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE127MKIT	Reperfusion Catheter ACE 60, 127 cm and Aspiration Tubing - KIT	MDN 4202	
5MAXACE132KIT	Reperfusion Catheter ACE 60, 132 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE132MKIT	Reperfusion Catheter ACE 60, 132 cm and Aspiration Tubing - KIT	MDN 1202	
5MAXACE064L115KIT	Reperfusion Catheter ACE 64, 115 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE064L115MKIT	Reperfusion Catheter ACE 64, 115 cm and Aspiration Tubing - KIT		
5MAXACE064L120KIT	Reperfusion Catheter ACE 64, 120 cm and Hi-Flow Aspiration Tubing - KIT	1 . 2	
5MAXACE064L120MKIT	Reperfusion Catheter ACE 64, 120 cm and Aspiration Tubing - KIT	L 1	
5MAXACE064L125KIT	Reperfusion Catheter ACE 64, 125 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE064L125MKIT	Reperfusion Catheter ACE 64, 125 cm and Aspiration Tubing - KIT		
5MAXACE064L127KIT	Reperfusion Catheter ACE 64, 127 cm and Hi-Flow Aspiration Tubing - KIT	754	DA IN
5MAXACE064L127MKIT	Reperfusion Catheter ACE 64, 127 cm and Aspiration Tubing - KIT		
5MAXACE064KIT	Reperfusion Catheter ACE 64, 132 cm and Hi-Flow Aspiration Tubing - KIT		100
5MAXACE064MKIT	Reperfusion Catheter ACE 64, 132 cm and Aspiration Tubing - KIT		
5MAXACE068L115HFKIT	Reperfusion Catheter ACE 68, 115 cm and Hi-Flow Aspiration Tubing - KIT		MINA
5MAXACE068L115KIT	Reperfusion Catheter ACE 68, 115 cm and Aspiration Tubing - KIT		WAY TY
5MAXACE068L120HFKIT	Reperfusion Catheter ACE 68, 120 cm and Hi-Flow Aspiration Tubing - KIT	ESSI	

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 6 of 11

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 763182 R000

Catalogue Number	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Reperfusion Catheter	+ Aspiration Tubing - KITs		
5MAXACE068L120KIT	Reperfusion Catheter ACE 68, 120 cm and Aspiration Tubing - KIT		
5MAXACE068L125HFKIT	Reperfusion Catheter ACE 68, 125 cm and Hi-Flow Aspiration Tubing - KIT	A dille	7.69
5MAXACE068L125KIT	Reperfusion Catheter ACE 68, 125 cm and Aspiration Tubing - KIT		A LOST
5MAXACE068L127HFKIT	Reperfusion Catheter ACE 68, 127 cm and Hi-Flow Aspiration Tubing - KIT		117 /
5MAXACE068L127KIT	Reperfusion Catheter ACE 68, 127 cm and Aspiration Tubing - KIT		
5MAXACE068HFKIT	Reperfusion Catheter ACE 68, 132 cm and Hi-Flow Aspiration Tubing - KIT	y ALE	
5MAXACE068KIT	Reperfusion Catheter ACE 68, 132 cm and Aspiration Tubing - KIT	AK W	A COUNTY OF THE PARTY OF THE PA
RED43HFKIT115	Reperfusion Catheter RED 43, 115 cm and Hi-Flow Aspiration Tubing - KIT	48" 1	
RED43KIT115	Reperfusion Catheter RED 43, 115 cm and Aspiration Tubing - KIT		
RED43HFKIT120	Reperfusion Catheter RED 43, 120 cm and Hi-Flow Aspiration Tubing - KIT		Call ?
RED43KIT120	Reperfusion Catheter RED 43, 120 cm and Aspiration Tubing - KIT		(87)
RED43HFKIT125	Reperfusion Catheter RED 43, 125 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT125	Reperfusion Catheter RED 43, 125 cm and Aspiration Tubing - KIT		
RED43HFKIT127	Reperfusion Catheter RED 43, 127 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT127	Reperfusion Catheter RED 43, 127 cm and Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
RED43HFKIT132	Reperfusion Catheter RED 43, 132 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT132	Reperfusion Catheter RED 43, 132 cm and Aspiration Tubing - KIT	ACCORD	
RED43HFKIT136	Reperfusion Catheter RED 43, 136 cm and Hi-Flow Aspiration Tubing - KIT	A 5 1 (
RED43KIT136	Reperfusion Catheter RED 43, 136 cm and Aspiration Tubing - KIT		
RED43HFKIT138	Reperfusion Catheter RED 43, 138 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT138	Reperfusion Catheter RED 43, 138 cm and Aspiration Tubing - KIT		
RED43HFKIT145	Reperfusion Catheter RED 43, 145 cm and Hi-Flow Aspiration Tubing - KIT		DA W
RED43KIT145	Reperfusion Catheter RED 43, 145 cm and Aspiration Tubing - KIT		
RED43HFKIT150	Reperfusion Catheter RED 43, 150 cm and Hi-Flow Aspiration Tubing - KIT		100
RED43KIT150	Reperfusion Catheter RED 43, 150 cm and Aspiration Tubing - KIT		
RED43HFKIT153	Reperfusion Catheter RED 43, 153 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT153	Reperfusion Catheter RED 43, 153 cm and Aspiration Tubing - KIT		A STATE
RED43HFKIT155	Reperfusion Catheter RED 43, 155 cm and Hi-Flow Aspiration Tubing - KIT	ESSI	
RED43KIT155	Reperfusion Catheter RED 43, 155 cm and Aspiration Tubing - KIT		

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 7 of 11

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 763182 R000

Catalogue Number Device Name		Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Reperfusion Catheter	+ Aspiration Tubing - KITs		
RED43HFKIT160	Reperfusion Catheter RED 43, 160 cm and Hi-Flow Aspiration Tubing - KIT		Land
RED43KIT160	Reperfusion Catheter RED 43, 160 cm and Aspiration Tubing - KIT	طاله حم	47.65
RED43HFKIT162	Reperfusion Catheter RED 43, 162 cm and Hi-Flow Aspiration Tubing - KIT		1 60 117
RED43KIT	Reperfusion Catheter RED 43, 162 cm and Aspiration Tubing - KIT		177
RED43HFKIT167	Reperfusion Catheter RED 43, 167 cm and Hi-Flow Aspiration Tubing - KIT	TO ASSESS	
RED43KIT167	Reperfusion Catheter RED 43, 167 cm and Aspiration Tubing - KIT	Y MIN	
RED62HFKIT115	Reperfusion Catheter RED 62, 115 cm and Hi-Flow Aspiration Tubing - KIT	AR W	
RED62KIT115	Reperfusion Catheter RED 62, 115 cm and Aspiration Tubing - KIT	- 48° T	The same of the sa
RED62HFKIT120	Reperfusion Catheter RED 62, 120 cm and Hi-Flow Aspiration Tubing - KIT		Complete Management
RED62KIT120	Reperfusion Catheter RED 62, 120 cm and Aspiration Tubing - KIT		Carl .
RED62HFKIT125	Reperfusion Catheter RED 62, 125 cm and Hi-Flow Aspiration Tubing - KIT		(5)
RED62KIT125	Reperfusion Catheter RED 62, 125 cm and Aspiration Tubing - KIT		THE WAY
RED62HFKIT132	Reperfusion Catheter RED 62, 132 cm and Hi-Flow Aspiration Tubing - KIT		
RED62KIT132	Reperfusion Catheter RED 62, 132 cm and Aspiration Tubing - KIT		
RED62SHFKIT	Reperfusion Catheter RED 62, 138 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
RED62SKIT	Reperfusion Catheter RED 62, 138 cm and Aspiration Tubing - KIT		
RED62HFKIT145	Reperfusion Catheter RED 62, 145 cm and Hi-Flow Aspiration Tubing - KIT	ACCIO	M. III III
RED62KIT145	Reperfusion Catheter RED 62, 145 cm and Aspiration Tubing - KIT	P - 10	
RED62HFKIT150	Reperfusion Catheter RED 62, 150 cm and Hi-Flow Aspiration Tubing - KIT	- 5	
RED62KIT150	Reperfusion Catheter RED 62, 150 cm and Aspiration Tubing - KIT		
RED62HFKIT155	Reperfusion Catheter RED 62, 155 cm and Hi-Flow Aspiration Tubing - KIT		
RED62KIT155	Reperfusion Catheter RED 62, 155 cm and Aspiration Tubing - KIT		DR W
RED62LHFKIT	Reperfusion Catheter RED 62, 160 cm and Hi-Flow Aspiration Tubing - KIT	4-11-11-12-12	
RED62LKIT	Reperfusion Catheter RED 62, 160 cm and Aspiration Tubing - KIT		100
RED68L115HFKIT	Reperfusion Catheter RED 68, 115 cm and Hi-Flow Aspiration Tubing - KIT	4	
RED68L115KIT	Reperfusion Catheter RED 68, 115 cm and Aspiration Tubing - KIT		
RED68L120HFKIT	Reperfusion Catheter RED 68, 120 cm and Hi-Flow Aspiration Tubing - KIT		A SULLING
RED68L120KIT	Reperfusion Catheter RED 68, 120 cm and Aspiration Tubing - KIT	BESSI	
RED68L125HFKIT	Reperfusion Catheter RED 68, 125 cm and Hi-Flow Aspiration Tubing - KIT		

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 8 of 11

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 763182 R000

Catalogue Number	Device Name	Type (Codes as per (EU) 2017/2185)	Variant Basic UDI-DI
Reperfusion Catheter	+ Aspiration Tubing - KITs		
RED68L125KIT	Reperfusion Catheter RED 68, 125 cm and Aspiration Tubing - KIT		
RED68L127HFKIT	Reperfusion Catheter RED 68, 127 cm and Hi-Flow Aspiration Tubing - KIT		47,650
RED68L127KIT	Reperfusion Catheter RED 68, 127 cm and Aspiration Tubing - KIT		
RED68HFKIT	Reperfusion Catheter RED 68, 132 cm and Hi-Flow Aspiration Tubing - KIT		117
RED68KIT	Reperfusion Catheter RED 68, 132 cm and Aspiration Tubing - KIT		
5MAXJET7L115KIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 115 cm and Hi-Flow Aspiration Tubing - KIT	Y ART	
5MAXJET7L115MKIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 115 cm and Aspiration Tubing - KIT	-9"	
5MAXJET7L120KIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 120 cm and Hi-Flow Aspiration Tubing - KIT	PAP	00
5MAXJET7L120MKIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 120 cm and Aspiration Tubing - KIT		
5MAXJET7L125KIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 125 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
5MAXJET7L125MKIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 125 cm and Aspiration Tubing - KIT	1 1000	
5MAXJET7L127KIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 127 cm and Hi-Flow Aspiration Tubing - KIT	200	
5MAXJET7L127MKIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 127 cm and Aspiration Tubing - KIT		
5MAXJET7KIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 132 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXJET7MKIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 132 cm and Aspiration Tubing - KIT	1860	
J7XKIT132	Reperfusion Catheter Penumbra JET 7 Standard Tip MAX, 132 cm and Hi-Flow Aspiration Tubing - KIT		To:

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 9 of 11

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 763182 R000

Catalogue Number	mber Device Name		Variant Basic UDI-DI
Reperfusion Catheter	+ Aspiration Tubing - KITs		
RED72L115HFKIT	Reperfusion Catheter RED 72, 115 cm and Hi-Flow Aspiration Tubing - KIT		
RED72L115KIT	Reperfusion Catheter RED 72, 115 cm and Aspiration Tubing - KIT		47.653
RED72L120HFKIT	Reperfusion Catheter RED 72, 120 cm and Hi-Flow Aspiration Tubing - KIT		A 1007
RED72L120KIT	Reperfusion Catheter RED 72, 120 cm and Aspiration Tubing - KIT		117
RED72L125HFKIT	Reperfusion Catheter RED 72, 125 cm and Hi-Flow Aspiration Tubing - KIT	7 2000	
RED72L125KIT	Reperfusion Catheter RED 72, 125 cm and Aspiration Tubing - KIT		
RED72L127HFKIT	Reperfusion Catheter RED 72, 127 cm and Hi-Flow Aspiration Tubing - KIT	AR W	
RED72L127KIT	Reperfusion Catheter RED 72, 127 cm and Aspiration Tubing - KIT	- 1 - 1	
RED72HFKIT	Reperfusion Catheter RED 72, 132 cm and Hi-Flow Aspiration Tubing - KIT		
RED72KIT	Reperfusion Catheter RED 72, 132 cm and Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
RED72SDHFKIT	Reperfusion Catheter RED 72 SENDit Technology, 132 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	001434001F3K11B4
RED72SDKIT	Reperfusion Catheter RED 72 SENDit Technology, 132 cm and Aspiration Tubing - KIT		
RED78KIT115	Reperfusion Catheter RED 78, 115 cm and Aspiration Tubing - KIT		
RED78KIT120	Reperfusion Catheter RED 78, 120 cm and Aspiration Tubing - KIT		
RED78KIT125	Reperfusion Catheter RED 78, 125 cm and Aspiration Tubing - KIT	1 COLOR	
RED78KIT127	Reperfusion Catheter RED 78, 127 cm and Aspiration Tubing - KIT	2 2 1	
RED78KIT	Reperfusion Catheter RED 78, 132 cm and Aspiration Tubing - KIT	1	A VOID
RED78KIT138	Reperfusion Catheter RED 78, 138 cm and Aspiration Tubing - KIT		A A A A A

First Issue Date: 2022-07-22 Starting Validity Date: 2024-03-21

Current Issue Date: **2024-03-21** Expiry Date: **2027-07-21**

...making excellence a habit."

Page 10 of 11

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 763182 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
2022-07-22	3597900	Issued
Current	3914683	Supplemented - Addition of devices and kit configurations of Reperfusion Catheter RED 43 and Reperfusion Catheter RED 78. Addition of kit configurations of RED 72 with SENDit Technology 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.

First Issue Date: **2022-07-22**

Expiry Date: **2027-07-21**

Current Issue Date: 2024-03-21

...making excellence a habit.™

Starting Validity Date: 2024-03-21

Page 11 of 11

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.