

EU Technical Documentation Assessment Certificate

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

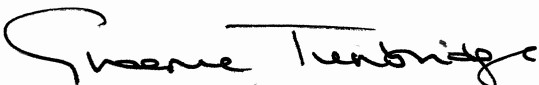
Address:

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**

Current Issue Date: **2024-03-21**

Starting Validity Date: **2024-03-21**

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

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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 Catheters			
PSC041	Reperfusion Catheter 041, 137 cm	MDN 1202	081454801PSCAT94
3MAXC	Reperfusion Catheter 3MAX, 160 cm		
4MAXC125	Reperfusion Catheter 4MAX, 125 cm		
4MAXC130	Reperfusion Catheter 4MAX, 130 cm		
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		
5MAXJETDL137	Reperfusion Catheter Penumbra JET D, 137 cm		
5MAXJETD	Reperfusion Catheter Penumbra JET D, 138 cm		
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		
5MAXACE064L115	Reperfusion Catheter ACE 64, 115 cm		
5MAXACE064L120	Reperfusion Catheter ACE 64, 120 cm		
5MAXACE064L125	Reperfusion Catheter ACE 64, 125 cm		
5MAXACE064L127	Reperfusion Catheter ACE 64, 127 cm		

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Reperfusion Catheters			
5MAXACE064	Reperfusion Catheter ACE 64, 132 cm	MDN 1202	081454801PSCAT94
5MAXACE068L115	Reperfusion Catheter ACE 68, 115 cm		
5MAXACE068L120	Reperfusion Catheter ACE 68, 120 cm		
5MAXACE068L125	Reperfusion Catheter ACE 68, 125 cm		
5MAXACE068L127	Reperfusion Catheter ACE 68, 127 cm		
5MAXACE068	Reperfusion Catheter ACE 68, 132 cm		
RED43115	Reperfusion Catheter RED 43, 115 cm		
RED43120	Reperfusion Catheter RED 43, 120 cm		
RED43125	Reperfusion Catheter RED 43, 125 cm		
RED43127	Reperfusion Catheter RED 43, 127 cm		
RED43132	Reperfusion Catheter RED 43, 132 cm		
RED43136	Reperfusion Catheter RED 43, 136 cm		
RED43138	Reperfusion Catheter RED 43, 138 cm		
RED43145	Reperfusion Catheter RED 43, 145 cm		
RED43150	Reperfusion Catheter RED 43, 150 cm		
RED43153	Reperfusion Catheter RED 43, 153 cm		
RED43155	Reperfusion Catheter RED 43, 155 cm		
RED43160	Reperfusion Catheter RED 43, 160 cm		
RED43	Reperfusion Catheter RED 43, 162 cm		
RED43167	Reperfusion Catheter RED 43, 167 cm		
RED62115	Reperfusion Catheter RED 62, 115 cm		
RED62120	Reperfusion Catheter RED 62, 120 cm		
RED62125	Reperfusion Catheter RED 62, 125 cm		
RED62132	Reperfusion Catheter RED 62, 132 cm		
RED62S	Reperfusion Catheter RED 62, 138 cm		
RED62145	Reperfusion Catheter RED 62, 145 cm		
RED62150	Reperfusion Catheter RED 62, 150 cm		
RED62155	Reperfusion Catheter RED 62, 155 cm		

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Reperfusion Catheters			
RED62L	Reperfusion Catheter RED 62, 160 cm	MDN 1202	081454801PSCAT94
RED68L115	Reperfusion Catheter RED 68, 115 cm		
RED68L120	Reperfusion Catheter RED 68, 120 cm		
RED68L125	Reperfusion Catheter RED 68, 125 cm		
RED68L127	Reperfusion Catheter RED 68, 127 cm		
RED68	Reperfusion Catheter RED 68, 132 cm		
5MAXJET7L115	Reperfusion Catheter Penumbra JET 7 Standard Tip, 115 cm		
5MAXJET7L120	Reperfusion Catheter Penumbra JET 7 Standard Tip, 120 cm		
5MAXJET7L125	Reperfusion Catheter Penumbra JET 7 Standard Tip, 125 cm		
5MAXJET7L127	Reperfusion Catheter Penumbra JET 7 Standard Tip, 127 cm		
5MAXJET7	Reperfusion Catheter Penumbra JET 7 Standard Tip, 132 cm		
RED72L115	Reperfusion Catheter RED 72, 115 cm		
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		
RED78120	Reperfusion Catheter RED 78, 120 cm		
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		

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Separators			
PSS041	Separator 041	MDN 1203	081454801PSSEPBO
3MAXS	Separator 3MAX		
PSF041	Separator 4MAX		
PSF054	Separator 5MAX		
3D Revascularization Device			
PSR3D	3D Revascularization Device	MDN 1203	081454801PSR3D98
Reperfusion Catheter + Aspiration Tubing - KITS			
3MAXCKIT	Reperfusion Catheter 3MAX, 160 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
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		
PSC054L127KIT	Reperfusion Catheter 5MAX, 127 cm and Hi-Flow Aspiration Tubing - KIT		
PSC054L127MKIT	Reperfusion Catheter 5MAX, 127 cm and Aspiration Tubing - KIT		
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		
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		

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Reperfusion Catheter + Aspiration Tubing - KITS			
5MAXJETDL137KIT	Reperfusion Catheter Penumbra JET D, 137 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
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		
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		
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		
5MAXACE125MKIT	Reperfusion Catheter ACE 60, 125 cm and Aspiration Tubing - KIT		
5MAXACE127KIT	Reperfusion Catheter ACE 60, 127 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE127MKIT	Reperfusion Catheter ACE 60, 127 cm and Aspiration Tubing - KIT		
5MAXACE132KIT	Reperfusion Catheter ACE 60, 132 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE132MKIT	Reperfusion Catheter ACE 60, 132 cm and Aspiration Tubing - KIT		
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		
5MAXACE064L120MKIT	Reperfusion Catheter ACE 64, 120 cm and Aspiration Tubing - KIT		
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		
5MAXACE064L127MKIT	Reperfusion Catheter ACE 64, 127 cm and Aspiration Tubing - KIT		
5MAXACE064KIT	Reperfusion Catheter ACE 64, 132 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE064MKIT	Reperfusion Catheter ACE 64, 132 cm and Aspiration Tubing - KIT		
5MAXACE068L115HFKIT	Reperfusion Catheter ACE 68, 115 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE068L115KIT	Reperfusion Catheter ACE 68, 115 cm and Aspiration Tubing - KIT		
5MAXACE068L120HFKIT	Reperfusion Catheter ACE 68, 120 cm and Hi-Flow Aspiration Tubing - KIT		

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Reperfusion Catheter + Aspiration Tubing - KITS			
5MAXACE068L120KIT	Reperfusion Catheter ACE 68, 120 cm and Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
5MAXACE068L125HFKIT	Reperfusion Catheter ACE 68, 125 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE068L125KIT	Reperfusion Catheter ACE 68, 125 cm and Aspiration Tubing - KIT		
5MAXACE068L127HFKIT	Reperfusion Catheter ACE 68, 127 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE068L127KIT	Reperfusion Catheter ACE 68, 127 cm and Aspiration Tubing - KIT		
5MAXACE068HFKIT	Reperfusion Catheter ACE 68, 132 cm and Hi-Flow Aspiration Tubing - KIT		
5MAXACE068KIT	Reperfusion Catheter ACE 68, 132 cm and Aspiration Tubing - KIT		
RED43HFKIT115	Reperfusion Catheter RED 43, 115 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT115	Reperfusion Catheter RED 43, 115 cm and Aspiration Tubing - KIT		
RED43HFKIT120	Reperfusion Catheter RED 43, 120 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT120	Reperfusion Catheter RED 43, 120 cm and Aspiration Tubing - KIT		
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		
RED43HFKIT132	Reperfusion Catheter RED 43, 132 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT132	Reperfusion Catheter RED 43, 132 cm and Aspiration Tubing - KIT		
RED43HFKIT136	Reperfusion Catheter RED 43, 136 cm and Hi-Flow Aspiration Tubing - KIT		
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		
RED43KIT145	Reperfusion Catheter RED 43, 145 cm and Aspiration Tubing - KIT		
RED43HFKIT150	Reperfusion Catheter RED 43, 150 cm and Hi-Flow Aspiration Tubing - KIT		
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		
RED43HFKIT155	Reperfusion Catheter RED 43, 155 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT155	Reperfusion Catheter RED 43, 155 cm and Aspiration Tubing - KIT		

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Reperfusion Catheter + Aspiration Tubing - KITs			
RED43HFKIT160	Reperfusion Catheter RED 43, 160 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
RED43KIT160	Reperfusion Catheter RED 43, 160 cm and Aspiration Tubing - KIT		
RED43HFKIT162	Reperfusion Catheter RED 43, 162 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT	Reperfusion Catheter RED 43, 162 cm and Aspiration Tubing - KIT		
RED43HFKIT167	Reperfusion Catheter RED 43, 167 cm and Hi-Flow Aspiration Tubing - KIT		
RED43KIT167	Reperfusion Catheter RED 43, 167 cm and Aspiration Tubing - KIT		
RED62HFKIT115	Reperfusion Catheter RED 62, 115 cm and Hi-Flow Aspiration Tubing - KIT		
RED62KIT115	Reperfusion Catheter RED 62, 115 cm and Aspiration Tubing - KIT		
RED62HFKIT120	Reperfusion Catheter RED 62, 120 cm and Hi-Flow Aspiration Tubing - KIT		
RED62KIT120	Reperfusion Catheter RED 62, 120 cm and Aspiration Tubing - KIT		
RED62HFKIT125	Reperfusion Catheter RED 62, 125 cm and Hi-Flow Aspiration Tubing - KIT		
RED62KIT125	Reperfusion Catheter RED 62, 125 cm and Aspiration Tubing - KIT		
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		
RED62SKIT	Reperfusion Catheter RED 62, 138 cm and Aspiration Tubing - KIT		
RED62HFKIT145	Reperfusion Catheter RED 62, 145 cm and Hi-Flow Aspiration Tubing - KIT		
RED62KIT145	Reperfusion Catheter RED 62, 145 cm and Aspiration Tubing - KIT		
RED62HFKIT150	Reperfusion Catheter RED 62, 150 cm and Hi-Flow Aspiration Tubing - KIT		
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		
RED62LHFKIT	Reperfusion Catheter RED 62, 160 cm and Hi-Flow Aspiration Tubing - KIT		
RED62LKIT	Reperfusion Catheter RED 62, 160 cm and Aspiration Tubing - KIT		
RED68L115HFKIT	Reperfusion Catheter RED 68, 115 cm and Hi-Flow Aspiration Tubing - KIT		
RED68L115KIT	Reperfusion Catheter RED 68, 115 cm and Aspiration Tubing - KIT		
RED68L120HFKIT	Reperfusion Catheter RED 68, 120 cm and Hi-Flow Aspiration Tubing - KIT		
RED68L120KIT	Reperfusion Catheter RED 68, 120 cm and Aspiration Tubing - KIT		
RED68L125HFKIT	Reperfusion Catheter RED 68, 125 cm and Hi-Flow Aspiration Tubing - KIT		

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Reperfusion Catheter + Aspiration Tubing - KITS			
RED68L125KIT	Reperfusion Catheter RED 68, 125 cm and Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
RED68L127HFKIT	Reperfusion Catheter RED 68, 127 cm and Hi-Flow Aspiration Tubing - KIT		
RED68L127KIT	Reperfusion Catheter RED 68, 127 cm and Aspiration Tubing - KIT		
RED68HFKIT	Reperfusion Catheter RED 68, 132 cm and Hi-Flow Aspiration Tubing - KIT		
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		
5MAXJET7L115MKIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 115 cm and Aspiration Tubing - KIT		
5MAXJET7L120KIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 120 cm and Hi-Flow Aspiration Tubing - KIT		
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		
5MAXJET7L125MKIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 125 cm and Aspiration Tubing - KIT		
5MAXJET7L127KIT	Reperfusion Catheter Penumbra JET 7 Standard Tip, 127 cm and Hi-Flow Aspiration Tubing - KIT		
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		
J7XKIT132	Reperfusion Catheter Penumbra JET 7 Standard Tip MAX, 132 cm and Hi-Flow Aspiration Tubing - KIT		

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Reperfusion Catheter + Aspiration Tubing - KITS			
RED72L115HFKIT	Reperfusion Catheter RED 72, 115 cm and Hi-Flow Aspiration Tubing - KIT	MDN 1202	081454801PSKITB4
RED72L115KIT	Reperfusion Catheter RED 72, 115 cm and Aspiration Tubing - KIT		
RED72L120HFKIT	Reperfusion Catheter RED 72, 120 cm and Hi-Flow Aspiration Tubing - KIT		
RED72L120KIT	Reperfusion Catheter RED 72, 120 cm and Aspiration Tubing - KIT		
RED72L125HFKIT	Reperfusion Catheter RED 72, 125 cm and Hi-Flow Aspiration Tubing - KIT		
RED72L125KIT	Reperfusion Catheter RED 72, 125 cm and Aspiration Tubing - KIT		
RED72L127HFKIT	Reperfusion Catheter RED 72, 127 cm and Hi-Flow Aspiration Tubing - KIT		
RED72L127KIT	Reperfusion Catheter RED 72, 127 cm and Aspiration Tubing - KIT		
RED72HFKIT	Reperfusion Catheter RED 72, 132 cm and Hi-Flow Aspiration Tubing - KIT		
RED72KIT	Reperfusion Catheter RED 72, 132 cm and Aspiration Tubing - KIT		
RED72SDHFKIT	Reperfusion Catheter RED 72 SENDit Technology, 132 cm and Hi-Flow Aspiration Tubing - KIT		
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		
RED78KIT127	Reperfusion Catheter RED 78, 127 cm and Aspiration Tubing - KIT		
RED78KIT	Reperfusion Catheter RED 78, 132 cm and Aspiration Tubing - KIT		
RED78KIT138	Reperfusion Catheter RED 78, 138 cm and Aspiration Tubing - KIT		

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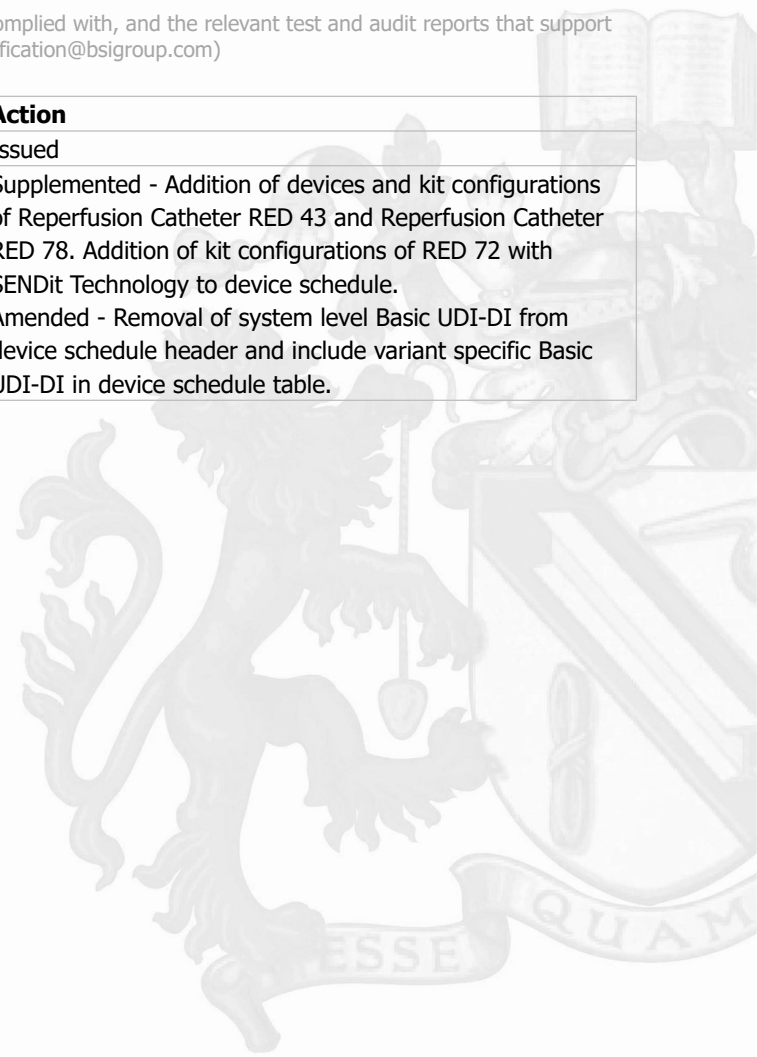
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Certificate History

(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
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.



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