EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 750915 R000

Manufacturer: Abbott Medical

Address:
177 County Road B East
St. Paul
Minnesota
55117
USA

Single Registration Number: US-MF-000018613

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II 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: **2022-04-21**

Current Issue Date: **2022-11-29**

Starting Validity Date: **2022-11-29**

Expiry Date: **2027-04-20**

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By Royal Charter

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EU Authorised Representative: Abbott Medical

Address:
The Corporate Village
Da Vincilaan 11 Box F1
1935
Zaventem
Belgium

EU Authorised Representative: Abbott Vascular International BVBA

Address:
Park Lane, Culliganlaan 2B
1831 Diegem
Belgium

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Device Schedule: Class III device

Class III, Implantable	**Intended purpose**
Amplatzer™ Talisman™ PFO Occlusion System	See MDR 751010
Navitor™ Transcatheter Aortic Valve	See MDR 751017
Amplatzer™ Amulet™ Left Atrial Appendage Occluder	See MDR 751008
Portico™ Transcatheter Aortic Valve	See MDR 751019
MitraClip G4 System	See MDR 751009
Class III	**Intended purpose**
FlexNav™ Delivery System	See MDR 751005
Amplatzer™ Steerable Delivery Sheath	See MDR 750953
Class IIb, Implantable	**Intended purpose**
Amplatzer™ Vascular Plug, Amplatzer™ Vascular Plug II, Amplatzer™ Vascular Plug 4	See MDR 767903

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	**Risk Classification**
Transcatheter Heart Valve Loading System	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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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
2022-04-21	3447260	Issued
2022-08-16	3682747	Amended – Addition of subcontractors. Addition of service for subcontractor: Microbiology service. Removal of services for subcontractor: Labelling and packaging. Supplemented - Addition of Navitor™ Transcatheter Aortic Valve, FlexNav™ Delivery System, Amplatzer™ Amulet™ Left Atrial Appendage Occluder, and Transcatheter Heart Valve Loading System.
2022-09-29	3677048	Amended – Addition of subcontractor.
2022-11-11	3795938	Supplemented – Addition of Portico™ Transcatheter Aortic Valve. Amended – Administrative update to previous entries Reference Number 3682747 and Reference Number 3677048.
Current	3766365	Supplemented – Addition of MitraClip G4 System, Amplatzer™ Steerable Delivery Sheath, and Amplatzer™ Vascular Plug, Amplatzer™ Vascular Plug II, Amplatzer™ Vascular Plug 4. Amended – Addition of subcontractor.

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