

# EU Quality Management System Certificate

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

## MDR 750915 R000

**Manufacturer:** Abbott Medical

**Address:**

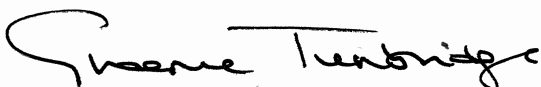
177 County Road B East  
St. Paul  
Minnesota  
55117  
USA

**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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## MDR 750915 R000

**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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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.

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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](mailto: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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