EU Technical Documentation Assessment Certificate

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

MDR 751008 R000

Manufacturer: Abbott Medical

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

Single Registration Number: US-MF-000018613

EU Authorised Representative: Abbott Medical

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

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 Issued: **2022-08-16** Date: **2022-08-16** Expiry Date: **2027-08-15**

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Device Schedule:

Device Name: Amplatzer™ Amulet™ Left Atrial Appendage Occluder

Basic UDI-DI: 5415067AMP1000DQ

Risk Classification: Class III Implantable

Intended Purpose as per the Instructions for Use:

The Amplatzer™ Amulet™ Left Atrial Appendage Occluder is a percutaneous, transcatheter device intended to occlude the left atrial appendage.

Type: MDN 1101

Model	Device Size (mm)	Disc Diameter (mm)	Lobe Diameter (mm)	Lobe Length (mm)
9-ACP2-007-016	16	22	16	7.5
9-ACP2-007-018	18	24	18	7.5
9-ACP2-007-020	20	26	20	7.5
9-ACP2-007-022	22	28	22	7.5
9-ACP2-010-025	25	32	25	10
9-ACP2-010-028	28	35	28	10
9-ACP2-010-031	31	38	31	10
9-ACP2-010-034	34	41	34	10

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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
Current	3447808	Issued

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