

# 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

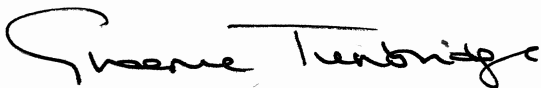
**Address:**

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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Page 1 of 3

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.  
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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](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
Current	3447808	Issued



First Issued: **2022-08-16**

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