EU Technical Documentation Assessment Certificate

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

MDR 751010 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: **2022-04-21** Date: **2022-04-21** Expiry Date: **2027-04-20**

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Device Schedule:

Device Name: Amplatzer™ Talisman™ PFO Occlusion System

Basic UDI-DI: 5415067AMP2000DX (system)

Device Name: Amplatzer™ Talisman™ PFO Occluder

Risk Classification: Class III Implantable

Intended Purpose as per the Instructions for Use:

The Amplatzer™ Talisman™ PFO Occluder is a percutaneous, transcatheter occlusion device intended to close a patent foramen ovale.

Type: MDN 1101

Basic UDI-DI: 5415067AMP2001DZ

Amplatzer™ Talisman™ PFO Occluder

Model	Right Atrial Disc Diameter (mm)	Left Atrial Disc Diameter (mm)
9-PFO-1818	18	18
9-PFO-2518	25	18
9-PFO-3025	30	25
9-PFO-3525	35	25

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Device Name: Amplatzer™ Talisman™ Delivery Sheath

Risk Classification: Class III

Intended Purpose as per the Instructions for Use:

The Amplatzer™ Talisman™ Delivery Sheath is intended to facilitate the delivery and deployment of an Amplatzer™ Talisman™ PFO Occluder.

Type: MDN 1203

Basic UDI-DI: 5415067AMP2002E3

Amplatzer™ Talisman™ Delivery Sheath

Model	French Size	Sheath Inner Diameter (mm)	Sheath Outer Diameter (mm)	Usable Length (cm)
9-TDS-08F45-80	8F	2.69	3.45	80
9-TDS-09F45-80	9F	3.00	3.81	80

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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	3447814	Issued

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