

# 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

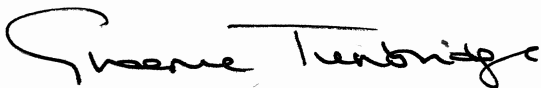
**Address:**

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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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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## MDR 751010 R000

### 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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**MDR 751010 R000**

## 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	3447814	Issued



First Issued: **2022-04-21**

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