Abbott Medical
177 County Road B East
St. Paul, MN 55117, USA
Tel: +1 855 478 5833

0072181 Rev. B

MDR Declaration of Conformity

Manufacturer:	Abbott Medical
Manufacturer SRN:	US-MF-000018613
Address:	177 County Road B East St. Paul, MN 55117 USA
Manufacturing Site(s):	Abbott Medical 5050 Nathan Lane North Plymouth, Minnesota 55442 USA
European Authorized Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Type:	Cardiac Occluder & Delivery System
Product Trade Name(s):	Amplatzer™ Talisman™ PFO Occlusion System Amplatzer™ Talisman™ PFO Occluder Amplatzer™ Talisman™ Delivery Sheath
Model Number(s):	Amplatzer™ Talisman™ PFO Occluder: 9-PFO-1818 9-PFO-2518 9-PFO-3025 9-PFO-3525 Amplatzer™ Talisman™ Delivery Sheath: 9-TDS-08F45-80 9-TDS-09F45-80

Signature: Teleshia Taylor De Sanchez Sr. Director Quality, Abbott Medical Structural Heart	26 April 2022 Issue Date On behalf of Abbott Medical, signed at 177 County Road B East, St. Paul, Minnesota 55117

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Intended Purpose:	Amplatzer™ Talisman™ PFO Occluder: The Amplatzer™ Talisman™ PFO Occluder is a percutaneous, transcatheter occlusion device intended to close a patent foramen ovale. Amplatzer™ Talisman™ Delivery Sheath: The Amplatzer™ Talisman™ Delivery Sheath is intended to facilitate the delivery and deployment of an Amplatzer™ Talisman PFO Occluder.
Risk Classification:	Amplatzer™ Talisman™ PFO Occluder: Class III, per Medical Device Regulation 2017/745, Annex VIII, Chapter III, Section 5.4 Amplatzer™ Talisman™ Delivery Sheath: Class III, per Medical Device Regulation 2017/745, Annex VIII, Chapter III, Section 5.2
Classification Rationale:	Amplatzer™ Talisman™ PFO Occluder: **Rule 8 -** All implantable devices and long-term surgically invasive devices are classified as class IIb unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III. Amplatzer™ Talisman™ Delivery Sheath: **Rule 6** - All surgically invasive devices intended for transient use are classified as class IIa unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III.
EMDN Code(s):	P07040303 - Cardiac Occluders, Patent Foramen Ovale And Patent Ductus Arteriosus C05 - Cardiovascular Introducing Sheaths
Basic UDI-DI:	Structural Intervention, Talisman System: 5415067AMP2000DX Structural Intervention, Talisman System (implant): 5415067AMP2001DZ

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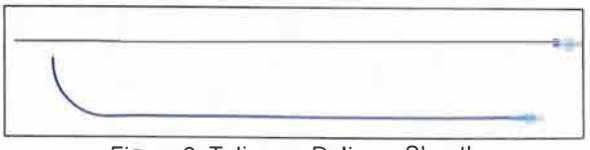
	Structural Intervention, Talisman Sheath (DS): 5415067AMP2002E3

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1 Directive 2006/42/EC on Machinery and Directive 89/686/EEC (and the superseding Regulation (EU) 2016/425) on Personal Protective Equipment do not apply.

Common Specifications Applied:	No applicable common specifications
STED #	0000044760
Notified Body:	BSI Group The Netherlands B.V. NB #: 2797 Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Supporting Certificate(s):	EC Certificate No: MDR 751010 R000 Expiration Date: 2027-04-20 QMS Certificate: MDR 750915 R000 Expiration: 2027-04-20
Original CE Mark Date:	2022-04-21
Conformity Assessment:	Annex IX
Device Photograph:	 Figure 1. Talisman Occluder  Figure 2. Talisman Delivery Sheath

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The products in the attached Declaration of Conformity Product List are approved under EC Certificate MDR 751010.

Declaration of Conformity Product List

Model No.	Description	UDI-DI
9-PFO-1818	Amplatzer Talisman PFO Occluder	05415067033307
9-PFO-2518	Amplatzer Talisman PFO Occluder	05415067033314
9-PFO-3025	Amplatzer Talisman PFO Occluder	05415067033321
9-PFO-3525	Amplatzer Talisman PFO Occluder	05415067033345
9-TDS-08F45-80	Amplatzer Talisman Delivery Sheath	05415067033352
9-TDS-09F45-80	Amplatzer Talisman Delivery Sheath	05415067033369

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