EU MDR Declaration of Conformity

MitraClip™ G4 System

Manufacturer's Name:	Abbott Medical
Manufacturer's Single Registration Number (SRN):	US-MF-000018613
Manufacturer's Address:	177 County Road B East St. Paul, MN 55117 USA
Authorized Representative's Name, Address, and Single Registration Number (SRN):	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium **SRN**: BE-AR-000002043
Product Trade Name(s):	MitraClip™ G4 System MitraClip™ G4 Clip Delivery System MitraClip™ G4 Steerable Guide Catheter
Model Number(s):	CDS0707 – NT CDS0707 – XT CDS0707 – NTW CDS0707 – XTW SGC0707
Intended Purpose:	The MitraClip™ G4 System is intended for reconstruction of the insufficient mitral valve through tissue approximation.
Risk Classification and Rule:	**Class III** **MitraClip™ G4 Clip Delivery System** Per Rule 8, Annex VIII, all implantable devices to be used in direct contact with the heart, the central circulatory system or the central nervous system are in Class III. Per Rule 7, Annex VIII, all surgically invasive devices intended for short-term use in direct contact with the heart and the central circulatory system are in Class III. **MitraClip ™ G4 Steerable Guide Catheter** Per Rule 7, Annex VIII, all surgically invasive devices intended for short-term use in direct contact with the heart and the central circulatory system are in Class III.
EMDN Code(s):	C03900299 – Beating Heart Cardiosurgery Devices - Other

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GMDN Code(s):	57790 - MitraClip G4 System 17846 - Steerable Guide Catheter
Basic UDI-DI:	MitraClip G4 Clip Delivery System – 5415067CLP1001EF MitraClip G4 Steerable Guide Catheter – 5415067CLP1002EH

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

I, the undersigned, for and on behalf of Abbott Medical, hereby declare that the medical device(s) specified above conform(s) with the applicable *General Safety & Performance Requirements* listed in Annex I and all relevant provisions of Regulation (EU) 2017/745.

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.

Conformity Assessment Procedure:
This declaration is made in accordance with Article 19 of the EU MDR 2017/745.

Supporting Certificate(s):

- Quality Management System Certificate: ISO 13485:2016 & EN ISO 13485:2016

Notified Body:

BSI Group The Netherlands B.V.
NB #: 2797
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Conformity Assessment Procedure:
Conformity assessment for MitraClip G4 System is based on a quality management system and assessment of the technical documentation as per Annex IX.

Supporting Certificate(s):

- EU Quality Management System Certificate: MDR 750915
- Technical Documentation Assessment Certificate Number: MDR 751009

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This signature section is applicable to all declarations of conformity, including to other European Union legislation, if applicable:

Prepared By: Irma Barr Date: June 12, 2023
Irma Barr, Senior Specialist Regulatory Affairs

Authorized Signatory: [signature] Date: 13 June 2023
Christopher Gallivan, Quality Person Responsible for Regulatory Compliance (PRRC)

Place of Issue: St. Paul, Minnesota, USA Issue Date: 13 June 2023