EC Declaration of Conformity

Legal Manufacturer:	*Edwards Lifesciences LLC* *One Edwards Way* *Irvine, CA 92614, USA*
Manufacturing Site(s):	*Edwards Lifesciences LLC* *12050 Lone Peak Parkway* *Draper, UT 84020 USA*
European Representative:	*Edwards Lifesciences Services GmbH* *Edisonstrasse 6* *85716 Unterschleissheim, Germany*
Product(s):	***Annuloplasty Rings*** *Model codes, Names: see following pages*
Product category:	***Cardiovascular Implants*** ***Prosthetic Rings for Treatment of Heart Valve Insufficiency*** *07 – Non-active implantable devices* *(according to EN ISO 15225)*
Classification:	*Class III / Rule 8* *(According to Annex IX of the MDD)*
Conformity Assessment Route:	*Annex II*
UMDNS / GMDN Codes:	*UMDNS: 16039 Annuloplasty Rings* *GMDN: 45577 Mitral Annuloplasty Ring* *GMDN: 45578 Mitral / Tricuspid Annuloplasty Ring*

We hereby declare that the distributed CE marked products specified in the attached product list, meet the provisions of the “EC-Directive”, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and any subsequent amendments. In addition, we declare that the listed products conform to applicable standards and the essential requirements listed in Annex I of the Directive. All supporting documentation is retained under the control of the Legal Manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directive that applies to them. This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system is described in the said CE Marking of Conformity Certificate, issued and delivered by TÜV SÜD Certification.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 80399 Münich Germany Identification Number 0123

The manufacturer has established and is maintaining a quality system that meets the requirements of the international standards indicated in the table below.

The directive and these standards are supported by the following certificates:

Certificate Number	Valid until	Issued by	Holder of Certificate
3821948 ISO 13485:2016 EN ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine
3817373 ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine
G1 039555 0201, Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH	Edwards Lifesciences LLC, Irvine
G7 039555 0206, Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH	Edwards Lifesciences LLC, Irvine

This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC.

Signed for and on behalf of Manufacturer
Signature and Date of Issue:

Debra Grodt

Digitally signed by Debra Grodt
DN: cn=Debra Grodt, o=Edwards Lifesciences, ou=Regulatory Affairs Director, email=debra_grodt@edwards.com, c=US
Reason: I am approving this document
Date: 2020.03.03 07:13:51 -08'00'

Debra Grodt *Date*
Director, Regulatory Affairs
Edwards Lifesciences LLC
Irvine, CA

Product List: Edwards Annuloplasty Rings

Trade Name and Sizes	Model(s)	Start of CE Marking
Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring Mitral Model 4100 with Holder *Sizes*: *24, 26, 28, 30, 32, 34 mm*	4100	02 Dec 2003
Carpentier-Edwards Physio Annuloplasty Ring Mitral with Holder *Sizes*: *24*, *26, 28, 30, 32, 34, 36, 38, 40 mm*	4450	08 May 2000
Cosgrove-Edwards Annuloplasty System with Template/Lanyard for Valvuloplasty *Sizes*: *26, 28, 30, 32, 34, 36, 38 mm*	4600	08 May 2000
Edwards MC3 Tricuspid Annuloplasty Ring with Template/Lanyard for Valvuloplasty *Sizes*: *26, 28, 30, 32, 34, 36 mm*	4900	15 July 2002
Carpentier-Edwards Physio II Annuloplasty Ring *Sizes*: *24*, *26, 28, 30, 32, 34, 36, 38, 40 mm*	5200	17 Oct 2008
Carpentier-Edwards Physio Tricuspid Annuloplasty Ring Model 6200 *Sizes*: *24*, *26, 28, 30, 32, 34, 36 mm*	6200	23 May 2011