

## **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** 

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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 Director, Regulatory Affairs Edwards Lifesciences LLC Irvine, CA Date

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## **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	4100	02 Dec 2003
Sizes: 24, 26, 28, 30, 32, 34 mm		
Carpentier-Edwards Physio Annuloplasty Ring Mitral with Holder	4450	08 May 2000
Sizes: 24, 26, 28, 30, 32, 34, 36, 38, 40 mm		00 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

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