Edwards

EC Declaration of Conformity

Manufacturer:	*Edwards Lifesciences LLC* *One Edwards Way* *Irvine, CA 92614, USA*
European Representative:	*Edwards Lifesciences Services GmbH* *Edisonstrasse 6* *85716 Unterschleissheim, Germany*
Product category:	*07 – Non-active implantable devices* *(according to EN ISO 15225)*
Products:	***Biological Heart Valve Substitutes*** *Model codes, Names: see following pages*
Classification:	*Class III / Rules 8 and 17* *(According to Annex IX of the MDD)*
Conformity Assessment Route:	*Annex II*
UMDNS / GMDN Nomenclature:	*UMDNS: 15870 Prostheses, Cardiac Valve, Biological* *GMDN: 60242 Aortic Heart Valve Bioprosthesis* *60244 Mitral Heart Valve Bioprosthesis*
Applicable Standards:	*The harmonized standards and other consensus standards used (specified by numbers, titles, editions and/or dates of issue) in relation to which conformity is declared, as well as the identification of internal data confirming compliance are provided in the Essential Requirements Checklists for the products identified in this declaration.*
Start of CE Marking:	*See following pages*

We herewith declare that the distributed CE marked products specified above conform to the products covered by the "CE Marking of Conformity Certificate" issued and delivered by DEKRA Certification B.V., in accordance with Annex II of the "EC-Directive," Council Directive 93/42/EEC of 14 June 1993, concerning Medical Devices and with the particular requirements laid down in Annex I of Commission Regulation 722/2012 of 8 August, 2012, concerning medical devices manufactured utilizing tissue of animal origin. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply 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 DEKRA Certification B.V.

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

These directive(s) and standard(s) are supported by the following certificates:

Certificate Number	Valid until	Issued by	Holder of Certificate	Facility(ies)
3817373 ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 17192 Daimler Irvine, CA 92614, USA 12050 Lone Peak Parkway Draper, UT 84020, USA 35 Changi North Crescent Singapore 499641 Singapore 1821 Kettering Irvine, CA 92614, USA La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica
3821948 ISO 13485:2016 EN ISO 13485:2016	2021-01-07	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA 17192 Daimler Irvine, CA 92614 USA 1821 Kettering Irvine, CA 92614 USA 12050 Lone Peak Parkway Draper, UT 84020 USA 35 Changi North Crescent Singapore 499641 Singapore La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica
2103732CE04	2024-05-26	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA
2103732DE04	2024-05-26	DEKRA Certification B.V.	Edwards Lifesciences LLC, Irvine	One Edwards Way Irvine, CA 92614, USA

Notified Body:

DEKRA Certification B.V
Meander 1051

6825 MJ Arnhem, The Netherlands
Identification Number 0344

Trade Name and Sizes	Model(s)	Start of CE Marking
Carpentier-Edwards® PERIMOUNT RSR® Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	2800TFX	April 2019
Carpentier-Edwards® PERIMOUNT Plus® Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	6900PTFX	April 2004
Carpentier-Edwards® PERIMOUNT® Magna Ease™ Pericardial Bioprosthesis [aortic] *Sizes: 19, 21, 23, 25, 27, 29 mm*	3300TFX	Dec 2006
Carpentier-Edwards® PERIMOUNT® Magna Mitral Ease™ Pericardial Bioprosthesis [mitral] *Sizes: 25, 27, 29, 31, 33 mm*	7300TFX	Aug 2010

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

Signed for and on behalf of
Manufacturer: *Edwards Lifesciences LLC*

Ashwini Jacob

Digitally signed by Ashwini Jacob
DN: cn=Ashwini Jacob, o=Edwards Lifesciences, ou=Sr. Director, Regulatory Affairs, email=ashwini_jacob@edwards.com, c=US
Date: 2019.09.30 16:08:23 -07'00'

Ashwini Jacob
Sr Director, Regulatory Affairs