EC CERTIFICATE

Number: 2103732CE04

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I with measuring function and in sterile condition)

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

For the product category(ies)

Biological Heart Valve Substitutes and Accessories and Pericardial Patches for Use in Heart Surgery

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 31 March 2010

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with the conformity of the devices with metrological requirements and with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August, 2012 concerning medical devices manufactured utilising tissue of animal origin. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024 Revised: 16 July 2019
Issued for the first time: 31 March 2010 Reissued: 1 October 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2103732CE04

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Biological Heart Valve Substitutes and Accessories and Pericardial Patches for Use in Heart Surgery

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

This certificate covers the following product(s):

Heart Valves, Animal Origin: Biological Heart Valve Substitutes and Accessories (Class III)
- Carpentier-Edwards PERIMOUNT Bioprosthesis Aortic and Mitral Heart Valves
- EDWARDS INTUITY Valves (aortic)
- EDWARDS INTUITY Delivery Systems
- Edwards Inflation Device (Class Is/ Im)

Patch of Animal Origin: Pericardial Patches (Class III)

Initial date: 31 March 2010
Revision date: 16 July 2019

DEKRA Certification B.V.

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