EC DESIGN-EXAMINATION CERTIFICATE

Number: 2103732DE04

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

For the product

Heart Valves, Animal Origin: Biological Heart Valve Substitutes

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
CE Marking of Conformity 2103732CE04
Addendum, initially dated 31 March 2010

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, 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, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of 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.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and 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: 4 January 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: 2103732DE04

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Heart Valves, Animal Origin: Biological Heart Valve Substitutes

Issued to:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

This certificate covers the following product(s):

Device Model	Description
2800TFX	Carpentier-Edwards® PERIMOUNT RSR® Pericardial Aortic Bioprosthesis Sizes 19, 21, 23, 25, 27, 29mm
3300TFX	Carpentier-Edwards® PERIMOUNT® Magna Ease Pericardial Aortic Bioprosthesis Sizes: 19, 21, 23, 25, 27 and 29mm
6900PTFX	Carpentier-Edwards® PERIMOUNT Plus® Mitral Bioprosthesis Sizes: 25, 27, 29, 31 and 33mm
7300TFX	Carpentier-Edwards® PERIMOUNT® Magna Mitral Ease™, Pericardial Bioprosthesis [mitral] Sizes: 25, 27, 29, 31 and 33 mm
11000A	Edwards® Pericardial Aortic Bioprosthesis Sizes 19, 21, 23, 25, 27 and 29mm
11000M	Edwards® Pericardial Mitral Bioprosthesis Sizes 25, 27, 29, 31, 33mm
11500A	INSPIRIS RESILIA™ Aortic Valve Sizes 19, 21, 23, 25, 27 and 29mm

Initial date: 31 March 2010
Revision date: 14 October 2019

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B.T.M. Holtus
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