EC CERTIFICATE

Number: 2016183CE01

Full Quality Assurance System

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

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

For the product category(ies)

Devices for Cardiac Surgery and Accessories

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 1 March 2002

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 for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. 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: 7 January 2023
Issued for the first time: 1 March 2002

Revised: 4 January 2019
Reissued: 7 January 2017

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2016183CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Devices for Cardiac Surgery and Accessories

Issued to:

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

This certificate covers the following product(s):

Cardioplegia
- Retrograde and Antegrade Cardioplegia Catheter (Class IIa)

Cardiopulmonary Bypass
- Arterial Cardiopulmonary Bypass Cannula (Class III)
- Heart Bypass Venous Drainage Cannula (Class III)
- Cardiopulmonary Bypass Vent Catheter (Class III)
- Atrial Vent Catheters (Class III)
- Cardiopulmonary Bypass Cannula Kits (Class III)

Accessories
- Valve Placement Devices (Class IIa)
- Vascular Tourniquet Sheath (Class IIa)
- Peripheral Venous Guidewire (Class IIa)
- Peripheral Arterial Guidewire (Class IIa)
- Introducer Sheath (Class IIa)
- Soft Tissue Retractors (Class IIa)
- Knot Pushers (Class IIa)
- Dilators (Class IIa)

Initial date: 1 March 2002
Revision date: 11 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
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