EC CERTIFICATE

Number: 2103732CE01

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 in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine CA 92614
United States Of America

For the product category(ies)

Systems for Heart Valve Repair and/or Replacement, 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 15 October 2007

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 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: 7 January 2023
Issued for the first time: 31 August 2007

Revised:23 July 2015
Reissued: 7 January 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
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
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2103732CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Systems for Heart Valve Repair and/or Replacement, and Accessories

Issued to:

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

Location	Activity
Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA	Production and Distribution of Heart Valve Delivery Systems, Valvuloplasty Catheters, Heart Valve Subassemblies (frames) and accessories (introducers, dilators and crimpers)
Edwards Lifesciences (Singapore) Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	Production of Biological Heart Valves and their subassemblies.
Edwards Lifesciences AG Altsagenstrasse 14 CH-6048 Horw Switzerland	Production and distribution of biological heart valves.
Edwards Lifesciences Services GmbH Edisonstrasse 6 D-85716 Unterschleissheim Germany	European Authorized Representative

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CE MARKING OF CONFORMITY
MEDICAL DEVICES

Systems for Heart Valve Repair and/or Replacement, and Accessories

Issued to:

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

This certificate covers the following product(s):

Transcatheter Bovine Aortic Heart Valves and Systems for Transfemoral Delivery
- RetroFlex™ Dilator Kit (Class IIa)
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- Edwards™ Transfemoral Balloon Catheter (Class III)
- Edwards™ Expandable Introducer Sheath Set (Class III)
- Edwards™ eSheath™ Introducer Set (Class III)
- NovaFlex+ Delivery System (Class III)
- Edwards SAPIEN 3™ Transcatheter Heart Valve (Class III)
- Edwards SAPIEN 3i™ Transcatheter Heart Valve (Class III)
- Edwards Commander™ Delivery System (Class III)

Transcatheter Bovine Pulmonic Heart Valves and Systems for Percutaneous Delivery
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- NovaFlex+ Delivery System (Class III)
- Edwards™ Transfemoral Balloon Catheter (Class III)
- RetroFlex™ Dilator Kit (Class IIa)
- Edwards™ Expandable Introducer Sheath Set (Class III)

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drs. G.J. Zoetbrood
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CE MARKING OF CONFORMITY
MEDICAL DEVICES

Systems for Heart Valve Repair and/or Replacement, and Accessories

Issued to:

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

This certificate covers the following product(s):

Transcatheter Bovine Aortic Heart Valves and Systems for Transapical and Transaortic Delivery
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- Ascendra+™ Delivery System (Class III)
- Ascendra+™ Introducer Sheath Set, (Class III)
- Ascendra™ Balloon Aortic Valvuloplasty Catheter (Class III)
- Edwards SAPIEN 3™Transcatheter Heart Valve (Class III)
- Edwards SAPIEN 3i™ Transcatheter Heart Valve (Class III)
- Edwards Certitude™ Delivery System (Class III)
- Edwards Certitude™ Introducer Sheath Set (Class III)

Transcatheter Bovine Aortic Heart Valves and Systems for Transapical, Transaortic and Transfemoral Implantation in Aortic and Mitral Surgical Valves
- Edwards SAPIEN XT™ Transcatheter Heart Valve (Class III)
- NovaFlex+™ Delivery System (Class III)
- Ascendra+™ Delivery System (Class III)
- Edwards™ Expandable Introducer Sheath Set (Class III)
- Ascendra+™ Introducer Sheath Set (Class III)
- RetroFlex™ Dilator Kit (Class IIa)

Accessories for Valve Delivery (Class I, sterile)
- Crimpers
- Crimp Stoppers
- Qualcrimp™ Crimping Accessory

Initial date: 15 October 2007
Revision date: 7 January 2018
DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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