CERTIFICATE

Number: 3821948

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Edwards Lifesciences LLC

One Edwards Way Irvine, CA 92614 **United States Of America**

including the implementation meets the requirements of the standard:

ISO 13485:2016 EN ISO 13485:2016

Scope: Design, development, production and distribution of:

- biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device);
- transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers);
- transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate);
- annuloplasty rings and accessories (handles, sizers, and trays);
- biologic pericardial patches for the area of heart valve replacement, repair and reconstruction; catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous
 - insertion kits.

Certificate expiry date: 7 January 2024 Certificate effective date: 8 June 2021 13 December 2018 Certified since:

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus Managing Director

J.A. van Vugt Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



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-product-safety.com Company registration 09085396

ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way Irvine, CA 92614 **United States Of America**

Certified organization(s) and/or locations:

Location	Certification scope / Activity
Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA	 Design, development, production and distribution of: biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); annuloplasty rings and accessories (handles, sizers, and trays); biologic pericardial patches for the area of heart valve replacement, repair and reconstruction; catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.
Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA	 Production and distribution of: biological surgical heart valve accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); transcatheter heart valve systems (biological heart valve delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); annuloplasty rings and accessories (handles, sizers, and trays); catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.

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ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way Irvine, CA 92614 United States Of America

Certified organization(s) and/or locations: continued

Location	Certification scope / Activity
Edwards Lifesciences (Singapore) Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	 Production and distribution of: biological surgical heart valves; transcatheter heart valve systems; transcatheter valve repair and replacement systems (implants).
Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca, Edificio	Production and distribution of: biological heart valve replacement subassemblies.
Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica	
Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica	Production and distribution of: • transcatheter heart valves.
Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	Production and distribution of: transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate).

Addendum expiry date: Addendum effective date: 7 January 2024 8 June 2021

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