

# 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).

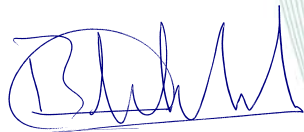
Certificate expiry date: 7 January 2024

Certificate effective date: 8 June 2021

Certified since: 13 December 2018

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





# 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: <ul style="list-style-type: none"> <li>biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device);</li> <li>transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers);</li> <li>transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate);</li> <li>annuloplasty rings and accessories (handles, sizers, and trays);</li> <li>biologic pericardial patches for the area of heart valve replacement, repair and reconstruction;</li> <li>catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits).</li> </ul>
Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA	Production and distribution of: <ul style="list-style-type: none"> <li>biological surgical heart valve accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device);</li> <li>transcatheter heart valve systems (biological heart valve delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers);</li> <li>transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate);</li> <li>annuloplasty rings and accessories (handles, sizers, and trays);</li> <li>catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits).</li> </ul>



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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: <ul style="list-style-type: none"> <li>biological surgical heart valves;</li> <li>transcatheter heart valve systems;</li> <li>transcatheter valve repair and replacement systems (implants).</li> </ul>
Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica	Production and distribution of: <ul style="list-style-type: none"> <li>biological heart valve replacement subassemblies.</li> </ul>
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: <ul style="list-style-type: none"> <li>transcatheter heart valves.</li> </ul>
Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	Production and distribution of: <ul style="list-style-type: none"> <li>transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate).</li> </ul>

Addendum expiry date: 7 January 2024

Addendum effective date: 8 June 2021