



CERTIFICATE

Certificate Registration No: 951 24 6154

**The Certification Body of
TÜV SÜD AMERICA INC.**

Certifies that the organization

Edwards Lifesciences
Zona Franca La Lima, de la entrada de Pequeño
Mundo 100 mts oeste y 200 mts sur.
Cartago, 03016 Costa Rica

for the scope

Manufacturing of Heart Valves, Rings and Stents

has established and applies an Environmental Management System.
An audit was performed and has furnished proof that the requirements according to

ISO 14001:2015

are fulfilled.

The certificate is valid from November 5, 2024 until November 4, 2027
With a re-issue date on N/A

Michael Fernald
Head of Central Certification Body



TÜV SÜD America Inc • 401 Edgewater Place, Suite 500 • Wakefield, MA 01880 USA • www.TUVSUD.com

The validity of this certificate is contingent on the company maintaining its management system to the requirements of the indicated standard and is subject to regular monitoring by TÜV SÜD America.



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Manufacturing of Heart Valves, Rings and Stents

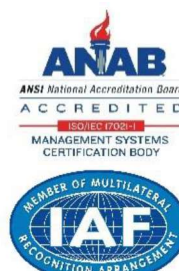
has established and applies an Occupational Health and Safety Management System.
An audit was performed and has furnished proof that the requirements according to

ISO 45001:2018

are fulfilled.

The certificate is valid from November 5, 2024 until November 4, 2027
With a re-issue date on N/A

Michael Fernald
Head of Central Certification Body



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CERTIFICATE

Certificate Registration No: 951 24 6116

The Certification Body of
TÜV SÜD AMERICA INC.

Certifies that the organization

Edwards Lifesciences Ireland Limited
National Technology Park
Limerick, V94 31X5 Ireland

for the scope

Production and distribution of: transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories and loading system, dilator kit, stabilizer incl. base and plate)

See attachment for complete listing of sites

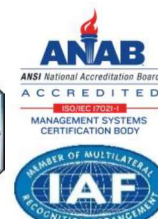
has established and applies an Environmental Management System.
An audit was performed and has furnished proof that the requirements according to

ISO 14001:2015

are fulfilled.

The certificate is valid from September 25, 2024 until September 24, 2027
With a re-issue date on N/A

Michael Fernald
Head of Central Certification Body
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CERTIFICATE

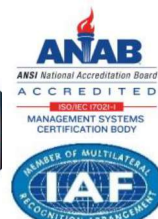
Certificate Registration No: 951 24 6116

Certificate Holder:

Edwards Lifesciences Ireland Limited
National Technology Park
Limerick, V94 31X5 Ireland

At the Sites	Specific Scope Site
Edwards Lifesciences Ireland Limited National Technology Park Limerick V94 31X5 Ireland	Central Function. Production and distribution of: transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories and loading system)
Edwards Lifesciences Ireland Limited 10 Earhart Avenue, Shannon Free Zone Shannon 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)

Michael Fernald
Head of Central Certification Body
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CERTIFICATE

Certificate Registration No: 951 24 6110

The Certification Body of
TÜV SÜD AMERICA INC.

Certifies that the organization

Edwards Lifesciences Ireland Limited
National Technology Park
Limerick, V94 31X5 Ireland

for the scope

Production and distribution of: transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories and loading system, dilator kit, stabilizer incl. base and plate)

See attachment for complete listing of sites

has established and applies an Occupational Health and Safety Management System. An audit was performed and has furnished proof that the requirements according to

ISO 45001:2018

are fulfilled.

The certificate is valid from September 25, 2024 until September 24, 2027
With a re-issue date on N/A

Michael Fernald
Head of Central Certification Body
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CERTIFICATE

Certificate Registration No: 951 24 6110

Certificate Holder:
Edwards Lifesciences Ireland Limited
 National Technology Park
 Limerick, V94 31X5 Ireland

At the Sites	Specific Scope Site
Edwards Lifesciences Ireland Limited National Technology Park Limerick V94 31X5 Ireland	Central Function. Production and distribution of: transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories and loading system)
Edwards Lifesciences Ireland Limited 10 Earhart Avenue, Shannon Free Zone Shannon 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)

Michael Fernald
 Head of Central Certification Body
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CERTIFICATE

Certificate Registration No: 951 24 6186

The Certification Body of
TÜV SÜD AMERICA INC.

Certifies that the organization

**Edwards Lifesciences Inc dba Edwards
Lifesciences LLC**
One Edwards Way
Irvine, CA 92614 USA

for the scope

**The Production and Distribution of Surgical and
Transcatheter Heart Valves and Pilot Operations
related to Heart Valve Delivery Systems and Valves**

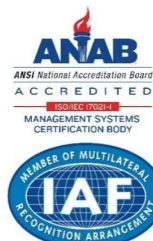
has established and applies a Environmental Management System.
An audit was performed and has furnished proof that the requirements
according to

ISO 14001:2015

are fulfilled.

The certificate is valid from November 27, 2024 until November 26, 2027 with a
re-issue date on N/A

Michael Fernald
Head of Central Certification Body



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TÜV®



CERTIFICATE

Certificate Registration No: 951 24 6185

**The Certification Body of
TÜV SÜD AMERICA INC.**

Certifies that the organization

**Edwards Lifesciences Inc dba Edwards
Lifesciences LLC**
One Edwards Way
Irvine, CA 92614 USA

for the scope

**The Production and Distribution of Surgical and
Transcatheter Heart Valves and Pilot Operations
related to Heart Valve Delivery Systems and Valves**

has established and applies an Occupational Health and Safety Management System.
An audit was performed and has furnished proof that the requirements according to

ISO 45001:2018

are fulfilled.

The certificate is valid from November 27, 2024 until November 26, 2027, with a
re-issue date on N/A

Michael Fernald
Head of Central Certification Body



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CERTIFICATE

Certificate Registration No: 951 24 6024

The Certification Body of
TÜV SÜD AMERICA INC.

Certifies that the organization



Edwards Lifesciences

**EDWARDS LIFESCIENCES
(SINGAPORE) PTE LTD**
35 CHANGI NORTH CRESCENT
SINGAPORE 499641 Republic of Singapore

for the scope

Production and Distribution of: biological surgical heart valves;
transcatheter heart valve systems; transcatheter valve repair and
replacement systems (implants).
Technical Area(s): Non-Active Implants

has established and applies an Environmental Management System.
An audit was performed and has furnished proof that the requirements according to

ISO 14001:2015

are fulfilled.

The certificate is valid from December 23, 2024 until October 25, 2027
With a re-issue date on N/A

Michael Fernald
Head of Central Certification Body



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CERTIFICATE

Certificate Registration No: 951 24 6026

The Certification Body of
TÜV SÜD AMERICA INC.

Certifies that the organization



Edwards Lifesciences

**EDWARDS LIFESCIENCES
(SINGAPORE) PTE LTD**
35 CHANGI NORTH CRESCENT
SINGAPORE 499641 Republic of Singapore

for the scope

Production and Distribution of: biological surgical heart valves;
transcatheter heart valve systems; transcatheter valve repair and
replacement systems (implants).
Technical Area(s): Non-Active Implants

has established and applies an Occupational Health and Safety Management System.
An audit was performed and has furnished proof that the requirements according to

ISO 45001:2018

are fulfilled.

The certificate is valid from September 27, 2022 until October 03, 2025
With a re-issue date on December 23, 2024

Michael Fernald
Head of Central Certification Body



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CERTIFICATE

Certificate Registration No: 951 23 5624

The Certification Body of
TÜV SÜD AMERICA INC.

Certifies that the organization

Edwards Lifesciences Sàrl
Route de l'Etraz 70
Nyon, 1260 Switzerland

for the scope

Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters

See attachment for complete listing of sites

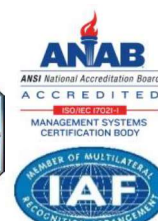
has established and applies an Electrostatic Discharge Control program.
An audit was performed and has furnished proof that the requirements according to

ISO 14001:2015

are fulfilled.

The certificate is valid from April 10, 2024 until April 9, 2027
With a re-issue date on N/A

Michael Fernald
Centralized Certification Body Manager
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CERTIFICATE

Certificate Registration No: 951 23 5624

Certificate Holder:

Edwards Lifesciences Sàrl

Route de l'Etraz 70

Nyon, 1260 Switzerland

At the Sites	Specific Scope Site
Edwards Lifesciences Sàrl Route de l'Etraz 70 Nyon, 1260 Switzerland	Central Function, Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
EDWARDS LIFESCIENCES HELLAS SP LTD 10 Kifissias Av., Maroussi, 15125 Greece	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
EDWARDS LIFESCIENCES, S.L. C/ NARCISO MONTURIOL, 11, PARQUE TECNOLÓGICO DE VALENCIA, BLOQUE A PATERNA V, 46980 Spain	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Czech Republic s.r.o. Praga Studios, Pernerova street 697/35 Prague 8, 18600 Czech Republic	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences GmbH Parkring 30 Garching bei 85748 München Germany	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Italia s.r.l. Centro Leoni, Edificio A, Via Giovanni Spadolini n° 5 Milan(MI), 20141 Italy	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences UK Ltd. 3 The Sector Newbury Business Park, Berkshire, RG14 2PZ United Kingdom	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Nordic AB Södra Långgatan 25 Malmö, 21144 Sweden	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters

Michael Fernald
Centralized Certification Body Manager
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Certificate Holder:

Edwards Lifesciences Sàrl

Route de l'Etraz 70

Nyon, 1260 Switzerland

At the Sites	Specific Scope Site
Edwards Lifesciences A/S c/o Regus Winghouse Ørestads Boulevard 73 Copenhagen S, 2300 Denmark	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Nordic AB, Filial i Finland c/o Regus Luna House Mannerheimintie 12B Helsinki, 00100 Finland	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Nordic AB NUF c/o Regus Nydalsveien 28 Oslo, 0484 Norway	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Austria GmbH Vorgartenstrasse 206C Vienna, 1020 Austria	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences SAS Immeuble Gershwin 1 Rue Arnold Schoenberg Guyancourt, 78280 France	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences BV Verlengde Poolseweg 16 Breda, 4818 CL Netherlands	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Belgium BV Pontbeekstraat 4 - 3rd floor Dilbeek, 1702 Belgium	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Poland Sp. z oo. Equator, Al. Jerozolimskie 100 Warszawa, 00-807 Poland	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters

Michael Fernald
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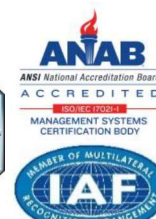
Edwards Lifesciences Sàrl

Route de l'Etraz 70

Nyon, 1260 Switzerland

At the Sites	Specific Scope Site
Edwards Lifesciences (Portugal) Lda Rua das Lagoas Pequenas Edificio 5B – Piso 0 Porto Salvo, 2744-017 Portugal	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Sàrl Praga Studios, Pernerova street 697/35 Prague 8, 18600 Czech Republic	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters
Edwards Lifesciences Ltd. 5th floor Beaux Lane House, Mercer Street Lower Dublin, D02 Ireland	Import, Distribution and Sales of Vascular and Cardiovascular Devices. Import, Distribution, Sales and Technical Training, Repair and Sales of Spare Parts for Monitoring Systems for Metabolic and Cardiovascular Parameters

Michael Fernald
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