



CERTIFIES THAT THE
ENVIRONMENTAL MANAGEMENT SYSTEM
ESTABLISHED AT

EDWARDS LIFESCIENCES

Parque Industrial Itabo, Carretera Sánchez Km 18.5
Haina, República Dominicana

Complies with:

ISO 14001:2015

The scope of certification includes:
Manufacturing not elsewhere classified (IAF Code 23)

Manufacturing, warehouse, and packaging of medical devices.

CERTIFICATION DATE:	2021-09-16
REGISTRATION No.:	R20210916-03
EXPIRATION DATE:	2024-09-15
ACCREDITATION No.:	AMSCB-0914-002-16



For the Certification Board

Celso Alvarado

Celso Alvarado
PRESIDENT

This certificate is property of QSI Auditing & Certification Services, LLC,
618 E South Street, Suite 500, Orlando, FL 32801
Certification is validated periodically via Surveillance Audits.
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CS 9.0.0.0.2 VERSION F - DATE 2019-04-01





CERTIFIES THAT THE
OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM
ESTABLISHED AT

EDWARDS LIFESCIENCES

Parque Industrial Itabo, Carretera Sánchez Km 18.5
Haina, República Dominicana

Complies with:

ISO 45001:2018

The scope of certification includes:
Manufacturing not elsewhere classified (IAF Code 23)

Manufacturing, warehouse, and packaging of medical devices.

CERTIFICATION DATE:	2021-09-16
REGISTRATION No.:	R20210916-04
EXPIRATION DATE:	2024-09-15
ACCREDITATION No.:	AMSCB-0914-002-16



For the Certification Board

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CERTIFIES THAT THE
ENVIRONMENTAL MANAGEMENT SYSTEM
ESTABLISHED AT

EDWARDS LIFESCIENCES, LLC

One Edwards Way, Irvine
California, United States

Complies with:

ISO 14001:2015

The scope of certification includes:
Manufacturing not elsewhere classified (IAF Code 23)

Manufacturing of mixed plastic medical devices and
hand assembly of heart valve products, including supporting
functions such as warehousing, laboratory, and administrative activities.

CERTIFICATION DATE:	2021-03-10
REGISTRATION No.:	R20211003-02
EXPIRATION DATE:	2024-02-10
ACCREDITATION No.:	AMSCB-0914-002-16



ISO/IEC 17021-1
MANAGEMENT SYSTEM
CERTIFICATION BODY
ACCREDITATION NO.
AMSCB-0914-002-16



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One Edwards Way, Irvine
California, United States

Complies with:

ISO 45001:2018

The scope of certification includes:
Manufacturing not elsewhere classified (IAF Code 23)

Manufacturing of mixed plastic medical devices and
hand assembly of heart valve products, including supporting
functions such as warehousing, laboratory, and administrative activities.

CERTIFICATION DATE:	2021-03-10
REGISTRATION No.:	R20211003-03
EXPIRATION DATE:	2024-02-10
ACCREDITATION No.:	AMSCB-0914-002-16



For the Certification Board

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CERTIFIES THAT THE
ENVIRONMENTAL MANAGEMENT SYSTEM
ESTABLISHED AT

EDWARDS LIFESCIENCES

PO Box 1577 Añasco, Puerto Rico 00610

Complies with:

ISO 14001:2015

The scope of certification includes:

Manufacturing not elsewhere classified (IAF Code 23)
Manufacturing and sterilization of mixed plastic medical devices and
Hand assembly of hemodynamic monitoring disposable products
Including supporting operations such as warehousing,
Laboratory and administrative activities

CERTIFICATION DATE: 2021-02-10
REGISTRATION No.: R20210210-03
EXPIRATION DATE: 2024-02-09
ACCREDITATION No.: AMSCB-0914-002-16



For the Certification Board

Celso Alvarado
Celso Alvarado
PRESIDENT

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CERTIFIES THAT THE
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ESTABLISHED AT

EDWARDS LIFESCIENCES

PO Box 1577 Añasco, Puerto Rico 00610

Complies with:

ISO 45001:2018

The scope of certification includes:

Manufacturing not elsewhere classified (IAF Code 23)
Manufacturing and sterilization of mixed plastic medical devices and
Hand assembly of hemodynamic monitoring disposable products
Including supporting operations such as warehousing,
Laboratory and administrative activities

CERTIFICATION DATE:	2021-02-10
REGISTRATION No.:	R20210210-04
EXPIRATION DATE:	2024-02-09
ACCREDITATION No.:	AMSCB-0914-002-16



For the Certification Board

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Celso Alvarado
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CS 9.0.0.0.2 VERSION F - DATE 2019-04-01





PSB Singapore

CERTIFICATE

The Certification Body
of TÜV SÜD PSB Pte Ltd

certifies that



Edwards Lifesciences

EDWARDS LIFESCIENCES (SINGAPORE) PTE. LTD

35 Changi North Crescent
Singapore 499641

has established and applies
an Environmental Management System for

Production of Biological Heart Valves and their Subassemblies

Proof has been furnished that the requirements
according to

ISO 14001 : 2015

are fulfilled. The certificate is valid from **2021-11-06** to **2024-10-25**

Certificate Registration No. **2015-0660**

Date of Print : **2021-11-08**

Original Certification Date: 2015-10-26

Recertification audit date: 2021-09-15 to 2021-09-17

Last Certification Expiry Date: 2021-10-25



SIEW Kwai Heng, Tiffany
Head of Certification Body
Management Systems
Business Assurance Division



Page 1 of 1

Please refer to www.tuvsud.com/en-sg for current certificate status in the "Directory of Management System Certified Companies".

◆ CERTIFICAT

◆ CERTIFICADO

◆ СЕРТИФИКАТ

◆ 認證證書

◆ CERTIFICATE

◆ ZERTIFIKAT



PSB Singapore

CERTIFICATE

The Certification Body
of TÜV SÜD PSB Pte Ltd

certifies that

EDWARDS LIFESCIENCES (SINGAPORE) PTE. LTD
35 Changi North Crescent
Singapore 499641

has established and applies
an Occupational Health and Safety Management System for

Production of Biological Heart Valves and their subassemblies

Proof has been furnished that the requirements
according to

ISO 45001 : 2018

are fulfilled. The certificate is valid from **2019-10-04** to **2022-10-03**

Certificate Registration No. **OHS-45001-2019-0058**

Date of Print : **2019-10-07**



SIEW Kwai Heng, Tiffany
Certification Manager
Business Assurance Division
Management Systems



Page 1 of 1

Please refer to www.tuv-sud-psb.sg for current certificate status in the "Directory of Management System Certified Companies".



CERTIFIES THAT THE
ENVIRONMENTAL MANAGEMENT SYSTEM
ESTABLISHED AT

EDWARDS LIFESCIENCES

Cartago, Costa Rica

Complies with:

ISO 14001:2015

The scope of certification includes:
Manufacturing not elsewhere classified (IAF Code 23)
Manufactura de stents y válvulas cardiacas

CERTIFICATION DATE:	2020-07-10
REGISTRATION No.:	R20200710-01
EXPIRATION DATE:	2023-07-09
ACREDITATION No.:	AMSCB-0914-002-16



For the Certification Board

Celso Alvarado

Celso Alvarado
PRESIDENT

This certificate is property of QSI Auditing & Certification Services, LLC,
618 E South Street, Suite 500, Orlando, FL 32801

Certification is validated periodically via Surveillance Audits.

To validate this certificate please scan the QR code or visit: www.qsicertifications.com/validate

CS 9.0.0.0.2 VERSION F - DATE 2019-04-01





CERTIFIES THAT THE
ENVIRONMENTAL MANAGEMENT SYSTEM
ESTABLISHED AT

EDWARDS LIFESCIENCES, LLC.

12050 Lone Peak Parkway, Draper, UT 84020, USA.

Complies with:

ISO 14001:2015

The scope of certification includes:

Manufacturing not elsewhere classified (IAF Code 23)
The manufacturing of mixed plastic medical devices
and hand assembly of heart valve products.

CERTIFICATION DATE:	2020-28-10
REGISTRATION No.:	R20201028-02
EXPIRATION DATE:	2023-27-10
ACREDITATION No.:	AMSCB-0914-002-16



For the Certification Board

Celso Alvarado

Celso Alvarado
PRESIDENT

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618 E South Street, Suite 500, Orlando, FL 32801

Certification is validated periodically via Surveillance Audits.

To validate this certificate please scan the QR code or visit: www.qsicertifications.com/validate

CS 9.0.0.0.2 VERSION F - DATE 2019-04-01





Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that



Edwards

Edwards Lifesciences S.A.

Route de l'Etraz 70

1260 Nyon

Switzerland

including the sites and scope of application
see enclosure

has established and applies
an Environmental Management System.

An audit was performed, Order No. **707074551**.

Proof has been furnished that the requirements
according to

ISO 14001:2015

are fulfilled.

The certificate is valid from **2021-04-12** until **2024-04-09**.

Previous certificate valid until 2021-04-09.

Certificate Registration No.: **12 104 47536 TMS**.

Head of Certification Body
Munich, 2021-04-13





Management Service

Enclosure of Certificate Registration No.: 12 104 47536 TMS

Sites	Scope of application
Edwards Lifesciences S.A. Route de l'Etraz 70 1260 Nyon Switzerland	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. Parque Tecnológico de Valencia, Ronda Narciso Monturiol 11, Bloque A 46980 Paterna Spain	Distribution and sales of vascular and cardiovascular devices. Distribution, sales and repair for monitoring systems for metabolic and cardiovascular parameters.
Edwards Lifesciences AG, organizační složka Karolinská 661/4 186 00 Prague 8 - Karlín 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 Services GmbH Edisonstraße 6 85716 Unterschleißheim Germany	Distribution and sales of vascular and cardiovascular devices. 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	Distribution and sales of vascular and cardiovascular devices. Distribution, sales and repair for monitoring systems for metabolic and cardiovascular parameters.
Edwards Lifesciences SAS Immeuble Gershwin 1 Rue Arnold Schoenberg 78280 Guyancourt France	Distribution and sales of vascular and cardiovascular devices. 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 4818 CL Breda Netherlands	Distribution and sales of vascular and cardiovascular devices. 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 1702 Dilbeek Belgium	Distribution and sales of vascular and cardiovascular devices. Distribution, sales and repair for monitoring systems for metabolic and cardiovascular parameters.

Head of Certification Body
Munich, 2021-04-13





Management Service

Enclosure of Certificate Registration No.: 12 104 47536 TMS

Sites	Scope of application
Edwards Lifesciences (Portugal) Lda Rua das Lagoas Pequenas Edificio 5A - 5° Piso 2744-017 Porto Salvo Portugal	Distribution and sales of vascular and cardiovascular devices. Distribution, sales and repair for monitoring systems for metabolic and cardiovascular parameters.
Edwards Lifesciences Poland Sp. z oo. Equator, Al. Jerozolimskie 100 00-807 Warszawa Poland	
Edwards Lifesciences Czech Republic s.r.o. Praga Studios, Pernerova street 697/35 186 00 Prague 8 Czech Republic	Distribution and sales of vascular and cardiovascular devices. Distribution, sales and repair for monitoring systems for metabolic and cardiovascular parameters.
Edwards Lifesciences Italia s.r.l. Centro Leoni, Edificio A, Via Giovanni Spadolini n° 5 20141 Milan (MI) (MI) Italy	Distribution and sales of vascular and cardiovascular devices. 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 25 211 44 Malmö Sweden	
Edwards Lifesciences Nordic AB, Filial i Finland c/o Regus Luna House Mannerheimintie 12B 00100 Helsinki Finland	
Edwards Lifesciences Nordic AB NUF c/o Regus Nydalen Nydalsveien 33, Torgbygget 0484 Oslo Norway	
Edwards Lifesciences Austria GmbH Vorgartenstrasse 206C 1020 Vienna Austria	
Edwards Lifesciences Ltd. 5th floor Beaux Lane House, Mercer Street Lower Dublin D02 Ireland	
Edwards Lifesciences Ltd. 5th floor Beaux Lane House, Mercer Street Lower Dublin D02 Ireland	

Head of Certification Body
Munich, 2021-04-13



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

Enclosure of Certificate Registration No.: 12 104 47536 TMS

Sites	Scope of application
Edwards Lifesciences A/S Arne Jacobsens Allé 7, 5th floor 2300 Copenhagen S Denmark	Distribution and sales of vascular and cardiovascular devices. 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., 15125 Maroussi Greece	

CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

Head of Certification Body
Munich, 2021-04-13

