



Edwards Fogarty[®] Catheters.

The only name in clot
management backed
by over 50 years of
worldwide experience.



Edwards

For over 50 years, clinicians have counted on real Fogarty® catheters to address the real problem of clot management.

The reason is simple. Through collaboration and clinical learning, Edwards Lifesciences has continued to evolve and advance its Fogarty catheters to meet the exacting needs of specialists for vascular procedures. Their proven performance and manufacturing quality has led surgeons to specify genuine Fogarty catheters – available exclusively from Edwards – for millions of procedures worldwide.

Fresh, Soft Emboli/Thrombi

Fogarty Arterial Embolectomy Catheter

Simple, rapid removal of soft, fresh emboli and thrombi from the arterial system

- Hand-tied using a recessed winding technique to secure balloon to catheter
- Balloon exhibits a symmetry that exerts uniform contact with vessel walls for even pressure and precise traction
- Soft, rounded tip promotes easy insertion for reduced trauma

Fogarty Fortis Arterial Embolectomy Catheter

For more aggressive removal of emboli and thrombi from the arterial system

- Construction and materials designed to be more durable and withstand greater pull-force
- The addition of barium to the catheter shaft material provides radiopacity

Fresh, Soft Emboli/Thrombi, Temporary Occlusion, Infusion

Over-the-wire Fogarty Thru-Lumen Embolectomy Catheter

Multi-use, guidewire-compatible design enables removal of soft, fresh emboli and thrombi as well as fluid delivery, temporary occlusion, and blood sampling

- Tough, compliant Fogarty balloon conforms to the vessel to maximize clot removal while minimizing trauma
- Provides the solution for distal thrombus removal in the arterial system
- The addition of barium to the catheter shaft material and stainless steel markers proximal and distal to the balloon provide radiopacity

Mature, Adherent Thrombi

Fogarty Corkscrew Catheter

Used to dislodge adherent material in native vessels and synthetic grafts

- For extracting thrombus that is too resistant for an elastomeric balloon
- Corkscrew design increases the surface area for entrapping fibrous material
- Radiopaque and flexible

Fogarty Graft Thrombectomy Catheter

Designed for removing organized and adherent thrombus from synthetic grafts, such as aortofemoral grafts

- For thrombus that is too resistant for an elastomeric balloon
- Provides a larger diameter range than the Fogarty corkscrew catheter
- The pulling force can be varied by adjusting the diameter

Venous Thrombi

Fogarty Venous Thrombectomy Catheter

Designed for removing thrombi in the venous system

- The long, soft tip facilitates advancement past the venous valves without undue trauma

Fogarty Irrigation Catheter *(not shown)*

Can be used to heparinize the arterial tree following embolectomy or venous thrombectomy

You'll want a real

Fogarty®

Fogarty® Clot Management Catheters

Model Number	Usable Length (cm)	Catheter Size (F)	Membrane/Spiral Diameter Max. Extended (mm)	Membrane/Spiral Diameter Max. Retracted (mm)
FOGARTY CORKSCREW CATHETERS				
140806	80	4	2.7	6
140808	80	5	3.1	8
1408010	80	6	3.3	10
FOGARTY GRAFT THROMBECTOMY CATHETERS				
160245F	50	5	5.0	16
160246F	50	6	6.0	18

Model Number	Usable Length (cm)	Catheter Size (F)	Inflated Balloon Diameter (mm)	Max. Size of Deflated Balloon (F)	Max. Gas Capacity (ml)	Max. Liquid Capacity (ml)	Max. Recommended Pull Force (lbs.)	Compatible Introducer (F)	Compatible Guidewire (in.)
FOGARTY ARTERIAL EMBOLECTOMY CATHETERS (TUBE PACK)									
120602F	60	2	4	3.4	0.2	–	0.5	3.5	–
120403F	40	3	5	4.3	0.6	0.20	0.7	4	–
120803F	80	3	5	4.3	0.6	0.20	0.7	4	–
120404F	40	4	9	5.0	1.7	0.75	1.5	5	–
120804F	80	4	9	5.0	1.7	0.75	1.5	5	–
120805F	80	5	11	6.0	3.0	1.50	2.0	6	–
120806F	80	6	13	7.0	4.5	2.00	2.5	7	–
120807F	80	7	14	8.0	5.0	2.50	3.5	8	–
FOGARTY ARTERIAL EMBOLECTOMY CATHETERS (FLAT PACK WITH SYRINGE)									
12A0602F	60	2	4	3.4	0.2	–	0.5	3.5	–
12A0403F	40	3	5	4.3	0.6	2.0	0.7	4	–
12A0803F	80	3	5	4.3	0.6	2.0	0.7	4	–
12A0404F	40	4	9	5.0	1.7	0.75	1.5	5	–
12A0804F	80	4	9	5.0	1.7	0.75	1.5	5	–
12A1004F	100	4	9	5.0	1.7	0.75	1.5	5	–
12A0805F	80	5	11	6.0	3.0	1.50	2.0	6	–
12A0806F	80	6	13	7.0	4.5	2.00	2.5	7	–
12A0807F	80	7	14	8.0	5.0	2.50	3.5	8	–
FOGARTY FORTIS ARTERIAL EMBOLECTOMY CATHETERS									
120404FF	40	4	9	5.0	1.7	0.75	–	5	–
120804FF	80	4	9	5.0	1.7	0.75	–	5	–
OVER-THE-WIRE FOGARTY THRU-LUMEN EMBOLECTOMY CATHETERS									
12TLW403F	40	3	5	4.5	0.4	0.15	0.7	4.5	0.018
12TLW803F	80	3	5	4.5	0.4	0.15	0.7	4.5	0.018
12TLW1203F	120	3	5	4.5	0.4	0.15	0.7	4.5	0.018
12TLW404F	40	4	9	5.0	1.2	0.50	1.5	5	0.025
12TLW804F	80	4	9	5.0	1.2	0.50	1.5	5	0.025
12TLW405F35	40	5.5	11	6.0	1.7	0.90	2.0	6	0.035
12TLW805F35	80	5.5	11	6.0	1.7	0.90	2.0	6	0.035
12TLW406F	40	6	13	7.0	2.3	1.40	2.5	7	0.035
12TLW806F	80	6	13	7.0	2.3	1.40	2.5	7	0.035
12TLW807F	80	7	14	8.0	2.8	1.60	3.5	8	0.038
FOGARTY VENOUS THROMBECTOMY CATHETERS									
320806F	80	6	12	7.7	3.0	1.50	–	–	–
320808F	80	8	13	8.8	4.5	2.25	–	–	–
32080810F	80	8	19	10.0	8.0	4.00	–	–	–
FOGARTY IRRIGATION CATHETERS									
220804F	80	4	–	–	–	–	–	–	–
220806F	80	6	–	–	–	–	–	–	–
2202310F	23	10	–	–	–	–	–	–	–

Genuine Fogarty catheters are available exclusively from Edwards Lifesciences. To learn more, visit edwards.com/fogarty or call 800-FOGARTY.

For professional use. CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com





Edwards

EC Declaration of Conformity

Manufacturer:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614, USA

European Representative:

Edwards Lifesciences Services GmbH
Edisonstraße 6
85716 Unterschleißheim, Germany

Product category:

10 – Single Use Devices
(according to EN ISO 15225)

Product(-s):

Vascular Catheters, Clips & Clamp Inserts
Model codes, Names: see following pages

Classification:

See following pages
(According to Annex IX of the MDD)

Conformity Assessment Route:

Annex II

UMDNS / GMDN Nomenclature:

See following pages

Applicable Standard(-s):

See Essential Requirements Checklist of Technical File

Start of CE Marking:

See following pages

We herewith declare that the distributed CE marked products specified above conform to the product(s) covered by the "EC Certificate" issued and delivered by TÜV in accordance with Annex II (excluding Annex II.4) of the "EC Directive", Council Directive 93/42/EEC, concerning Medical Devices. This declaration of conformity is issued under the sole responsibility of Edwards Lifesciences LLC. All supporting documentation is retained at the premises of the manufacturer.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directives that apply to them.

The manufacturer has established and is maintaining a quality system which meets the requirements of EN ISO 13485:2016.

These directive(s) and standard(s) are supported by the following certificate(s):

Certificate Number	Valid until	Issued by	Holder of Certificate	Facility
G1 039555 0198	2024-05-26	TÜV SÜD Product Service	Edwards Lifesciences LLC, Irvine	Edwards Lifesciences LLC, Irvine*

*Denotes Design and Development facility

Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany
Identification Number 0123

Date: 30 Oct 2019

Irvine, U.S.A.

Karen Clement

Karen Clement
Senior Director, Regulatory Affairs
Critical Care
Edwards Lifesciences LLC

Fogarty® Arterial Embolectomy Catheters Tube-Pack Class IIa/ Rule 6 UMDNS code: 10714, Catheters, Embolectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
120403F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120403FS	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120404F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120602F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120803F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120803FS	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120804F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120805F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120806F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000
120807F	Fogarty® Arterial Embolectomy Catheters Tube-Pack	31 May 2000

Fogarty® FORTIS Arterial Embolectomy Catheters Tube-Pack Class IIa/ Rule 6 UMDNS code: 10714, Catheters, Embolectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
120404FF	Fogarty® FORTIS Arterial Embolectomy Catheters Tube-Pack	25 April 2005
120804FF	Fogarty® FORTIS Arterial Embolectomy Catheters Tube-Pack	25 April 2005

Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe) Class IIa/ Rule 6 UMDNS code: 10714, Catheters, Embolectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
12A0403F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A0404F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A0602F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A0803F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A0804F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A0805F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A0806F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A0807F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000
12A1004F	Fogarty® Arterial Embolectomy Catheters Flat-Pack (w/syringe)	31 May 2000

Fogarty® Arterial Embolectomy Catheter with gate valve Class IIa/ Rule 6 UMDNS code: 10714, Catheters, Embolectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
12GV0402F	Fogarty® Arterial Embolectomy Catheter with gate valve	12 January 2007

Fogarty® Thru-Lumen Embolectomy Catheters Class IIa/ Rule 6 UMDNS code: 10714, Catheters, Embolectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied (first Lot No.)
12TLW403F	Fogarty® Thru-Lumen Embolectomy Catheters	31 May 2000
12TLW404F	Fogarty® Thru-Lumen Embolectomy Catheters	31 May 2000
12TLW405F35	Fogarty® Thru-Lumen Embolectomy Catheters	23 August 2001
12TLW406F	Fogarty® Thru-Lumen Embolectomy Catheters	31 May 2000
12TLW803F	Fogarty® Thru-Lumen Embolectomy Catheters	31 May 2000
12TLW804F	Fogarty® Thru-Lumen Embolectomy Catheters	31 May 2000
12TLW805F35	Fogarty® Thru-Lumen Embolectomy Catheters	23 August 2001
12TLW806F	Fogarty® Thru-Lumen Embolectomy Catheters	31 May 2000
12TLW807F	Fogarty® Thru-Lumen Embolectomy Catheters	31 May 2000
12TLW1203F	Fogarty® Thru-Lumen Embolectomy Catheters	24 August 2007/ (58407197)

Fogarty® Adherent Clot Catheters Class IIa/ Rule 6 UMDNS code: 10756, Catheters, Thrombectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
140806	Fogarty® Corkscrew Catheters	31 May 2000
140808	Fogarty® Corkscrew Catheters	31 May 2000
1408010	Fogarty® Corkscrew Catheters	31 May 2000

Fogarty® Graft Thrombectomy Catheters Class IIa/ Rule 6 UMDNS code: 10756, Catheters, Thrombectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
160245F	Fogarty® Graft Thrombectomy Catheters	31 May 2000
160246F	Fogarty® Graft Thrombectomy Catheters	31 May 2000

Fogarty® Venous Thrombectomy Catheters Class IIa/ Rule 6 UMDNS code: 10756, Catheters, Thrombectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
320806F	Fogarty® Venous Thrombectomy Catheters	31 May 2000
320808F	Fogarty® Venous Thrombectomy Catheters	31 May 2000
32080810F	Fogarty® Venous Thrombectomy Catheters	31 May 2000

Fogarty® Irrigation Catheters Class IIa/ Rule 6 UMDNS code: 10730, Catheters, Irrigation (GMDN code: 10730)		
Model Code	Name	Date CE Marking first applied
220804F	Fogarty® Irrigation Catheters	31 May 2000

220806F	Fogarty® Irrigation Catheters	31 May 2000
2202310F	Fogarty® Irrigation Catheters	31 May 2000

Fogarty® Biliary Balloon Probes Class IIa/ Rule 6 UMDNS code: 10756, Catheters, Thrombectomy (GMDN code: 10696 Biliary drainage catheter)		
Model Code	Name	Date CE Marking first applied
410235F	Fogarty® Biliary Balloon Probes	31 May 2000
410236F	Fogarty® Biliary Balloon Probes	31 May 2000
410405F	Fogarty® Biliary Balloon Probes	31 May 2000

Fogarty® Occlusion Catheters Tube-Pack Class IIa/ Rule 6 UMDNS code: 10736, Catheters, Occlusion (GMDN code: 32584 Intravascular occluding catheter)		
Model Code	Name	Date CE Marking first applied
620403F	Fogarty® Occlusion Catheters Tube-Pack	31 May 2000
620404F	Fogarty® Occlusion Catheters Tube-Pack	31 May 2000
620405F	Fogarty® Occlusion Catheters Tube-Pack	31 May 2000

Laparoscopic Cholangiography Catheter Class IIa/ Rule 6 UMDNS code: 16429, Catheters, Cholangiography (GMDN code: 16429)		
Model Code	Name	Date CE Marking first applied
420804F	Laparoscopic Cholangiography Catheter	31 May 2000

Cholangiography Catheter Class IIa/ Rule 6 UMDNS code: 16429, Catheters, Cholangiography (GMDN code: 16429)		
Model Code	Name	Date CE Marking first applied
420404F	Cholangiography Catheter	31 May 2000
420406F	Cholangiography Catheter	31 May 2000

Cholangiography Kit Class IIa/ Rule 6 UMDNS code: 16429, Catheters, Cholangiography (GMDN code: 16429)		
Model Code	Name	Date CE Marking first applied
CV8000	Cholangiography Kit	31 May 2000

2F Embolectomy Catheter with Gate Valve Accessory Kit Class IIa/ Rule 6 UMDNS code: 10714, Catheters, Embolectomy (GMDN code: 58174 Thrombectomy balloon catheter)		
Model Code	Name	Date CE Marking first applied
CV3200	2F Embolectomy Catheter with Gate Valve Accessory Kit	31 May 2000

Fogarty® Softjaw Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
SOFT33	Fogarty® Softjaw Insert Sets	31 May 2000
SOFT61	Fogarty® Softjaw Insert Sets	31 May 2000
SOFT86	Fogarty® Softjaw Insert Sets	31 May 2000

Fogarty® Double Softjaw Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
DSOFT33	Fogarty® Double Softjaw Insert Sets	31 May 2000
DSOFT61	Fogarty® Double Softjaw Insert Sets	31 May 2000
DSOFT86	Fogarty® Double Softjaw Insert Sets	31 May 2000

EverGrip® Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
EVERGRIP33	EverGrip™ Insert Sets	3 February 2000
EVERGRIP61	EverGrip™ Insert Sets	3 February 2000
EVERGRIP86	EverGrip™ Insert Sets	3 February 2000

Fogarty® Safejaw® Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
SAFE33	Fogarty® Safejaw® Insert Sets	31 May 2000
SAFE61	Fogarty® Safejaw® Insert Sets	31 May 2000
SAFE86	Fogarty® Safejaw® Insert Sets	31 May 2000

Fogarty® Double Safejaw® Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
DSAFE33	Fogarty® Double Safejaw® Insert Sets	31 May 2000
DSAFE61	Fogarty® Double Safejaw® Insert Sets	31 May 2000
DSAFE86	Fogarty® Double Safejaw® Insert Sets	31 May 2000

Fogarty® Hydrajaw Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
HYDRA33	Fogarty® Hydrajaw Insert Sets	31 May 2000
HYDRA61	Fogarty® Hydrajaw Insert Sets	31 May 2000
HYDRA86	Fogarty® Hydrajaw Insert Sets	31 May 2000

Fogarty® Double Hydrajaw Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
DHYDRA33	Fogarty® Double Hydrajaw Insert Sets	31 May 2000
DHYDRA61	Fogarty® Double Hydrajaw Insert Sets	31 May 2000
DHYDRA86	Fogarty® Double Hydrajaw Insert Sets	31 May 2000

Fogarty® Safejaw® Hydrajaw Insert Sets Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
SAFEHY33	Fogarty® Safejaw® Hydrajaw Insert Sets	31 May 2000
SAFEHY61	Fogarty® Safejaw® Hydrajaw Insert Sets	31 May 2000
SAFEHY86	Fogarty® Safejaw® Hydrajaw Insert Sets	31 May 2000

Fogarty® Parallel Jaw Spring Clips Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
CPARAL6	Fogarty® Parallel Jaw Spring Clips	31 May 2000
CPARAL12	Fogarty® Parallel Jaw Spring Clips	31 May 2000

Fogarty® Softjaw Spring Clips Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
CSOFT6	Fogarty® Softjaw Spring Clips	31 May 2000
CSOFT12	Fogarty® Softjaw Spring Clips	31 May 2000

Fogarty® Everclip Spring Clips Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
EVERCLIP6	Fogarty® Everclip Spring Clips	27 October 2003

Fogarty® Safejaw® Spring Clips Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
CSAFE6	Fogarty® Safejaw® Spring Clips	31 May 2000

Fogarty® Double Safejaw® Spring Clips Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN codes: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
CDSAFE6	Fogarty® Double Safejaw® Spring Clips	31 May 2000

Fogarty® Handleless Clamp, Single Softjaw Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
HCSOFT10	Fogarty® Handleless Clamp, Single Softjaw	31 May 2000

Fogarty® Handleless Clamp, Double Softjaw Class IIa/ Rule 6 UMDNS code: 16028, Clips, Vascular (GMDN code: 47068 Vascular clamp, single-use)		
Model Code	Name	Date CE Marking first applied
HCDSOFT8	Fogarty® Handleless Clamp, Double Softjaw	31 May 2000

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).

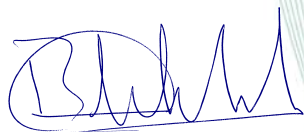
Certificate expiry date: 7 January 2024

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"> 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: <ul style="list-style-type: none"> 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).

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: <ul style="list-style-type: none"> 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 Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica	Production and distribution of: <ul style="list-style-type: none"> biological heart valve replacement subassemblies.
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"> transcatheter heart valves.
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"> 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: 7 January 2024

Addendum effective date: 8 June 2021



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039555 0198 Rev. 00

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine CA 92614
USA

Product Category(ies):

- Hemodynamic Monitoring Equipment
- Hemodynamic Monitoring Disposables
- Medical Devices used for the Diagnosis of Coronary Artery Disease
- Medical Devices used in the Diagnosis and Treatment of Peripheral Vascular Disease
- Medical Devices for the Treatment of Diseases of the Heart and the Central Circulatory System

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72150159

Valid from: 2019-10-29

Valid until: 2024-05-26

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 039555 0198 Rev. 00

Facility(ies):

**Edwards Lifesciences AG, Parque Industrial Itabo
Km 18.5 CARR.Sanchez, Haina, San Cristobal, DOMINICAN
REPUBLIC**

Edwards Lifesciences Technology Sàrl
State Road 402, Km 1.4, Industrial Park, 00610-1577 Añasco,
PUERTO RICO USA

Edwards Lifesciences LLC
One Edwards Way, Irvine CA 92614, USA

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Certificate

No. Q5 039555 0207 Rev. 00

Holder of Certificate: **Edwards Lifesciences LLC**

One Edwards Way
Irvine CA 92614
USA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Hemodynamic Monitoring Equipment, Disposables and Related Accessories; Medical Devices used for the Diagnosis of Coronary Artery Disease; Medical Devices and Related Accessories used in the Diagnosis and Treatment of Peripheral Vascular Disease; Medical Devices used in Support of Cardiopulmonary Bypass Surgery; EtO Sterilization Services and Respective Microbiological and Chemical Tests (Añasco)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 72157269

Valid from: 2020-06-07

Valid until: 2023-06-06

Date, 2020-05-14

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 039555 0207 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Edwards Lifesciences LLC
One Edwards Way, Irvine CA 92614, USA

Edwards Lifesciences Technology Sàrl
State Road 402, Km 1.4, Industrial Park, 00610-1577 Añasco,
PUERTO RICO USA

Edwards Lifesciences AG, Parque Industrial Itabo
Km 18.5 CARR.Sanchez, Haina, San Cristobal, DOMINICAN
REPUBLIC

Parameters: