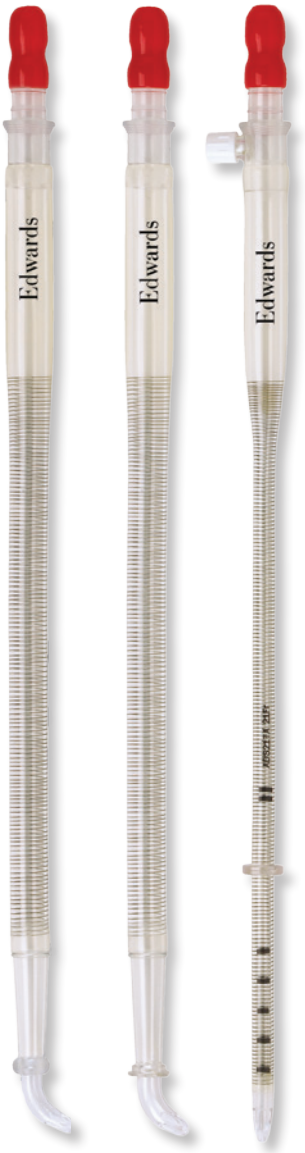
EZ Glide

Aortic Cannulae

Gentle, dispersive flow

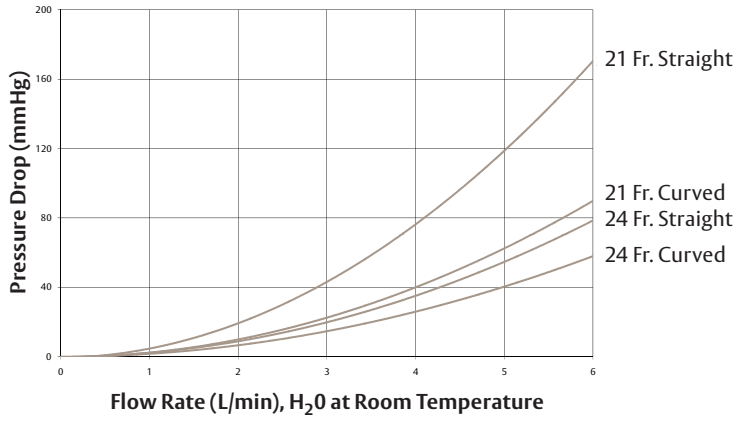


When cardiovascular surgery requires aortic cannulae, EZ Glide aortic cannulae are intended to help protect patients from the potential dangers of embolic dislodgement.

The unique auto dilating tip disperses flow in a gentle, conical spray pattern which reduces the likelihood of embolic disruption by reducing the exit force and line pressure.

- Optimized tip angle provides centered flow inside the aorta, away from the vessel wall
- Unique, auto-dilating tip enables ease of insertion
- Available with suture bump, suture flange, or moveable suture ring
- Depth markings aid in placement

Pressure Drop vs Flow



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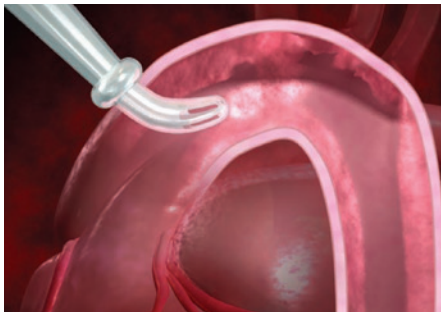
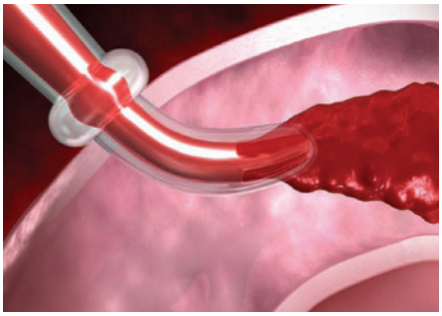
Flow through EZ Glide aortic cannulae



Central orientation of aortic cannula



Central fan shaped dispersive flow

By putting a new level of gentle, dispersive flow into a cannula, our enhanced EZ Glide aortic cannulae help you protect patients from the potential dangers of embolic dislodgement.

EZ Glide aortic cannulae offer:

- Central orientation designed to reduce jetting against the aortic wall
- Central fan shaped dispersive flow

EZ Glide aortic cannulae models

Model Number	Tip Configuration	Size	Connector	Vent Cap
EZC21A	Curved tip with suture bump	21 Fr. (7.0 mm)	3/8" Non-vented	Standard
EZC24A		24 Fr. (8.0 mm)		Standard
EZC21TA		21 Fr. (7.0 mm)	3/8" Vented	Standard
EZC24TA		24 Fr. (8.0 mm)		Standard
EZF21A	Curved tip with suture flange	21 Fr. (7.0 mm)	3/8" Non-vented	Standard
EZF24A		24 Fr. (8.0 mm)		Standard
EZF21TA		21 Fr. (7.0 mm)	3/8" Vented	Standard
EZF24TA		24 Fr. (8.0 mm)		Standard
EZS21A	Straight tip with suture flange	21 Fr. (7.0 mm)	3/8" Non-vented	Standard
EZS24A		24 Fr. (8.0 mm)		Standard
EZS21TA		21 Fr. (7.0 mm)	3/8" Vented	Standard
EZS21QTA		21 Fr. (7.0 mm)		Quick venting cap
EZS24TA		24 Fr. (8.0 mm)		Standard

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.

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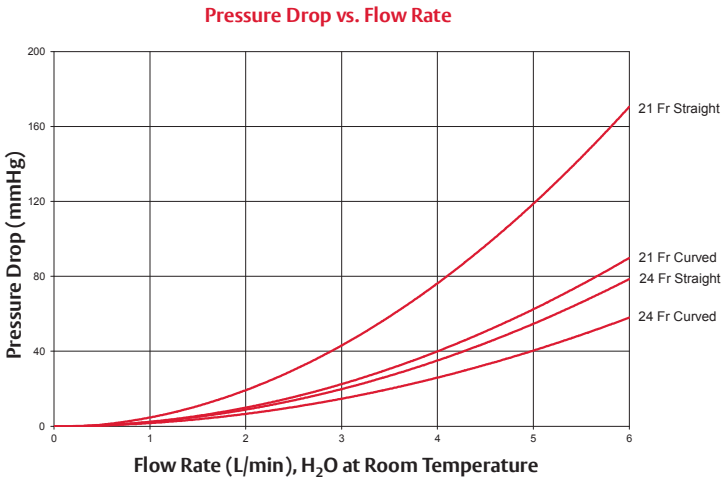
EZ Glide Aortic Perfusion Cannula

The EZ Glide aortic perfusion cannula is intended to create a dispersive flow.

- Tip design disperses return flow in a conical spray pattern
- Unique auto-dilating tip

10 units per case



Straight Cannula

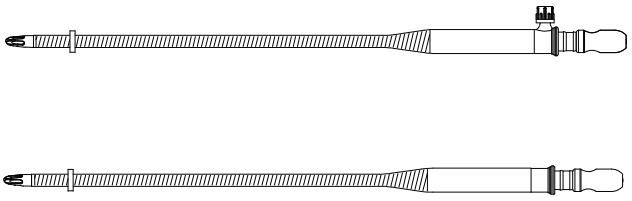
14 inch (35 cm) overall length

3/8 inch vented connector

EZS21TA	21 Fr (7.0 mm)
EZS24TA	24 Fr (8.0 mm)

3/8 inch non-vented connector

EZS21A	21 Fr (7.0 mm)
EZS24A	24 Fr (8.0 mm)



EC CERTIFICATE

Number: 2016183CE01

Full Quality Assurance System

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

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

For the product category(ies)

Devices for Cardiac Surgery and Accessories

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 1 March 2002

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 7 January 2023
Issued for the first time: 1 March 2002

Revised: 4 January 2019
Reissued: 7 January 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2016183CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Devices for Cardiac Surgery and Accessories

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

This certificate covers the following product(s):

Cardioplegia
- Retrograde and Antegrade Cardioplegia Catheter (Class IIa)

Cardiopulmonary Bypass
- Arterial Cardiopulmonary Bypass Cannula (Class III)
- Heart Bypass Venous Drainage Cannula (Class III)
- Cardiopulmonary Bypass Vent Catheter (Class III)
- Atrial Vent Catheters (Class III)
- Cardiopulmonary Bypass Cannula Kits (Class III)

Accessories
- Valve Placement Devices (Class IIa)
- Vascular Tourniquet Sheath (Class IIa)
- Peripheral Venous Guidewire (Class IIa)
- Peripheral Arterial Guidewire (Class IIa)
- Introducer Sheath (Class IIa)
- Soft Tissue Retractors (Class IIa)
- Knot Pushers (Class IIa)
- Dilators (Class IIa)

Initial date: 1 March 2002
Revision date: 11 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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EC DESIGN-EXAMINATION CERTIFICATE

Number: 2016183DE10

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

For the product

Arterial Cardiopulmonary Bypass Cannula

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 23 April 2019

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 23 April 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2016183DE10

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Arterial Cardiopulmonary Bypass Cannula

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

This certificate covers the following product(s):

EZ Glide Aortic Cannula models: EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A, EZS24TA

OptiSite Arterial Perfusion Cannula models: OPTI16, OPTI18, OPTI20, OPTI22

EndoReturn Arterial Cannula models: ER21B, ER23B

Initial date: 23 April 2019
Revision date: 26 April 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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-certification.com Company registration 09085396

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

MGMT. SYS. RvA C 589

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.

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 Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica	Production and distribution of: • 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: • 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: 7 January 2024
Addendum effective date: 8 June 2021

Edwards

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 **Classification**	*Arterial Cannula* *Class III - Annex IX, Rule 7 (AutoIncisor Rule 6)*
Conformity Assessment	*Annex II*
UMDNS / GMDN Nomenclature	*See following pages*

We hereby declare that the distributed CE marked products, specified in the annexed product list, meet the provisions of the Council Directive 93/42/EEC, as amended by 2007/47/EC concerning Medical Devices and that this Declaration of Conformity is issued under the sole responsibility of Edwards Lifesciences LLC. All supporting documentation is retained under the premises of the production location.

The manufacturer has established and is maintaining a quality system which meets the requirements of ISO 13485:2016 and EN ISO 13485:2016, per certificates **3817373** and **3821948** valid until 07 January 2021.

Notified Body	*DEKRA Certification B.V* *Meander 1051* *6825 MJ Arnhem, The Netherlands* *Identification Number 0344*
EC Certificate	*2016183CE01* *(Valid until 7 January 2023)* *2016183DE10* *(Valid until 26 May 2024)*
Signed for and on behalf of Manufacturer	*Edwards Lifesciences LLC* *Irvine, CA*

Ashwini Jacob

Digitally signed by Ashwini Jacob
DN: cn=Ashwini Jacob, o=Edwards Lifesciences, ou=Sr. Director, Regulatory Affairs, email=ashwini_jacob@edwards.com, c=US
Date: 2019.08.08 15:05:34 -07'00'

Ashwini Jacob
Sr. Director, Regulatory Affairs
Irvine, CA USA

Edwards

PRODUCT LIST
Arterial Cannula

This product list belongs to the Declaration of Conformity identified by ***Arterial Cannula*****,** and specifies that these CE marked products distributed by Edwards Lifesciences are in conformity with the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC concerning medical devices. The following list identifies the catalog number and description. Refer to the Essential Requirements Checklist for a list of relevant harmonized standards.

Start Date of CE Marking: Devices covered by this section of the Declaration were first CE Marked in 1998.

Catalog Number	**Description**
Arterial Cannula	**UMDNS: 15768 Cannulae, Aortic** **GMDN: 34893 Cardiopulmonary bypass cannula, arterial**
EZC21A	EZ Glide Aortic Cannula: Curved w/Suture Bump w/straight connector, 21 Fr.
EZC21TA	EZ Glide Aortic Cannula: Curved w/Suture Bump w/T connector, 21 Fr.
EZC24A	EZ Glide Aortic Cannula: Curved w/Suture Bump w/straight connector, 24 Fr.
EZC24TA	EZ Glide Aortic Cannula: Curved w/Suture Bump w/T connector, 24 Fr.
EZF21A	EZ Glide Aortic Cannula: Curved w/Suture Flange w/straight connector, 21 Fr.
EZF21TA	EZ Glide Aortic Cannula: Curved w/Suture Flange w/T connector, 21 Fr.
EZF24A	EZ Glide Aortic Cannula: Curved w/Suture Flange w/straight connector, 24 Fr.
EZF24TA	EZ Glide Aortic Cannula: Curved w/Suture Flange w/T connector, 24 Fr.
EZS21A	EZ Glide Aortic Cannula: Straight w/straight connector, 21 Fr.
EZS21TA	EZ Glide Aortic Cannula: Straight w/T connector, 21 Fr.
EZS24A	EZ Glide Aortic Cannula: Straight w/straight connector, 24 Fr.
EZS24TA	EZ Glide Aortic Cannula: Straight w/T connector, 24 Fr.
Catalog Number	**Description**
Arterial Cannula	**UMDNS: 10564 Cannulae, Arterial** **GMDN: 34893 Cardiopulmonary bypass cannula, arterial**
OPTI16	OptiSite Arterial Perfusion Cannula, 16 Fr., blunt tip, vented introducer
OPTI18	OptiSite Arterial Perfusion Cannula, 18 Fr., blunt tip, vented introducer
OPTI20	OptiSite Arterial Perfusion Cannula, 20 Fr., blunt tip, vented introducer
OPTI22	OptiSite Arterial Perfusion Cannula, 22 Fr., blunt tip, vented introducer

ThruPort Systems Arterial Cannulae All lots manufactured prior to August 10, 2011 will still be branded with PORT ACCESS Systems.

Start Date of CE Marking: Devices covered by this section of the Declaration were first CE Marked in 1999.

Catalog Number	Description	
Arterial Cannula		**UMDNS: 10564 Cannulae, Arterial** **GMDN: 34893 Cardiopulmonary bypass cannula, arterial**
ER21B	EndoReturn Arterial Cannula Kit: (Y- connector w/smooth, inner radius), 21 Fr, with Guidewire	
ER23B	EndoReturn Arterial Cannula Kit: (Y- connector w/smooth, inner radius), 23 Fr, with Guidewire	