



Edwards

## DECLARATION OF CONFORMITY

<b>Manufacturer</b>	<i>Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614, USA</i>
<b>European Representative</b>	<i>Edwards Lifesciences Services GmbH Edisonstrasse 6 85716 Unterschleissheim, Germany</i>
<b>Product Category Classification</b>	<i>Arterial Cannula Class III - Annex IX, Rule 7 (AutoIncisor Rule 6)</i>
<b>Conformity Assessment</b>	<i>Annex II</i>
<b>UMDNS / GMDN Nomenclature</b>	<i>See following pages</i>

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.

<b>Notified Body</b>	<i>DEKRA Certification B.V Meander 1051 6825 MJ Arnhem, The Netherlands Identification Number 0344</i>
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<b>EC Certificate</b>	<i>2016183CE01 (Valid until 7 January 2023)</i>
	<i>2016183DE10 (Valid until 26 May 2024)</i>

<b>Signed for and on behalf of Manufacturer</b>	<i>Edwards Lifesciences LLC Irvine, CA</i>
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**Ashwini Jacob**

Digitally signed by Ashwini Jacob  
DN: cn=Ashwini Jacob, o=Edwards Lifesciences, ou=Sr.  
Director, Regulatory Affairs,  
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Date: 2019.08.08 15:05:34 -0700'

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



**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
<b>Arterial Cannula</b>	
<b>UMDNS: 15768 Cannulae, Aortic GMDN: 34893 Cardiopulmonary bypass cannula, arterial</b>	
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
<b>Arterial Cannula</b>	
<b>UMDNS: 10564 Cannulae, Arterial GMDN: 34893 Cardiopulmonary bypass cannula, arterial</b>	
OPT116	OptiSite Arterial Perfusion Cannula, 16 Fr., blunt tip, vented introducer
OPT118	OptiSite Arterial Perfusion Cannula, 18 Fr., blunt tip, vented introducer
OPT120	OptiSite Arterial Perfusion Cannula, 20 Fr., blunt tip, vented introducer
OPT122	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	
	<b>Arterial Cannula</b>	<b>UMDNS: 10564 Cannulae, Arterial GMDN: 34893 Cardiopulmonary bypass cannula, arterial</b>
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	