

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:

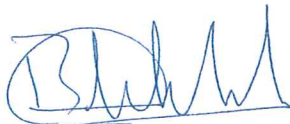
Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 23 April 2019

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

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

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ADDENDUM

Belonging to certificate: 2016183DE10

1/1

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):

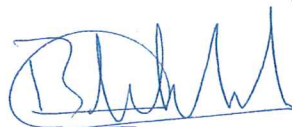
EZ Glide Aortic Cannula models: EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A, EZS24TA

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.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V'.

J.A. van Vugt
Certification Manager

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