Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 29.09.2023

Solicitantul FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, tel./fax: 022-273712, e-mail: contact@datacontrol.md
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Edwards Lifesciences
Arterial Cannula

EZC21A
EZC21TA
EZC24A
EZC24TA
EZF21A
EZF21TA
EZF24A
EZF24TA
EZS21A

EZS21TA
EZS24A
EZS24TA
OPTI16
OPTI18
OPTI20
OPTI22
ER21B
ER23B

Se anexează următoarele acte:
1) Declarație de Conformitate DoC: 046;
2) Certificarte CE no. 487703 MR2 din 29.04.2021.
3) EC Design-Examination Certificate no. 2016183DE10 din 23.04.2019.
4) Actul prin care producătorul își desemnează reprezentantul

Data 29.09.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Grabazei Alexandru
Date: 2023.09.29 16:05:37 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: FCPC DataControl S.R.L., cu sediul în or. Chișinău, str. N. Testemițanu 17/6, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Edwards Lifesciences
Arterial Cannula

EZC21A
EZC21TA
EZC24A
EZC24TA
EZF21A
EZF21TA
EZF24A
EZF24TA
EZS21A
EZS21TA
EZS24A
EZS24TA
OPTI16
OPTI18
OPTI20
OPTI22
ER21B
ER23B

Se anexează următoarele acte:

1) Declarație de Conformitate DoC: 046;
2) Certificarte CE no. 487703 MR2 din 29.04.2021.
3) EC Design-Examination Certificate no. 2016183DE10 din 23.04.2019.
4) Actul prin care producătorul își desemnează reprezentantul

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Grabazei Alexandru, director general. *Data 29.09.2023*

Cardiotech SRL
Str. Gheorghe Titeica, nr. 142, Etaj 5, 020304, Bucuresti, Romania

Edwards Lifesciences SA
Attn: Adrian Brannan
Route de l'Etraz
CH-1260 Nyon
Switzerland

February 26, 2020

Re: Authorization to appoint sub-distributor

Dear Adrian,

I refer to the distribution agreement between **Edwards Lifesciences SA** ("**Edwards**") and **Cardiotech S.R.L.** ("**Cardiotech**"), originally commencing on October 1, 2019 (the "**Agreement**").

Pursuant to Section 2.2 "Resellers" of the Agreement, Cardiotech requests Edwards consent, with effect from February 20, 2020 to appoint a sub-distributor, namely, **Data Control SRL** with its principal place of business at str. Testemitanu 17/6, bloc 7, scara 2 Chisinau Republica Moldova ("**Sub-Distributor**"), to perform for and on behalf of Cardiotech the rights granted in the Agreement to Cardiotech, I.e to re-sell the Products listed in Exhibit A of the Agreement in the "Territory of Moldova".

Cardiotech and Sub-Distributor understand and agree that Edwards' consent shall remain valid subject to the following conditions:

- Sub-Distributor shall comply with all national, EU and/or US-applicable laws, rules and regulations including those dealing with anti-fraud, anti-bribery, and anti-corruption, including, but not limited to the Foreign Corrupt Practices Act and the UK Bribery Act and comply with the ethical standards adopted by the MedTech Europe - trade association representing the medical technology industries in Europe ("MedTech Europe") with the MedTech Europe Code of Business Practice ("MedTech Europe Code") and/or the Guide for Medical Technology Sales & Marketing Intermediaries.;

- Sub-Distributor will not make any payments to or for the benefit of any government official, health care professional or of any customer for the purpose of obtaining business or obtaining any concession, or for any other improper purpose, and that it will strictly abide with any applicable national, EU or US laws and regulations related to foreign commerce, including, but not limited to, the Foreign Corrupt Practices Act, the UK Bribery Act, and anti-boycott legislation;

- Cardiotech shall immediately inform EDWARDS in writing of any information obtained or discovered during the term of the Agreement, relating to the Sub-Distributor' possible violations of the above conditions;

- Cardiotech will train all appropriate Sub-Distributor's employees providing services on behalf of Edwards regarding Edwards' policies and procedures for Interactions with Health Care Professionals and any anti-fraud, anti-bribery and anti-corruption laws.

Cardiotech SRL
Str. Gheorghe Titeica, nr. 142, Etaj 5, 020304, Bucuresti, Romania

Cardiotech understands and agrees that it shall remain fully responsible for the actions or omission of Sub-Distributor.

The sub-distributor Data Control S.R.L Moldova, undertakes to adhere and comply with all conditions imposed by the Manufacturer Edwards Lifescience S.A to the distributor Cardiotech S.R.L Romania, through the distribution agreement existing between the producer and the distributor.

Sub-Distributor consents in writing to be bound by the terms of the Agreement and to use its best efforts to perform the duties assumed by Sub-Distributor.

Edwards' consent remains valid as long as (i) compliance with the above conditions is effected and (ii) the Agreement is in force. Notwithstanding the foregoing, Edwards may at any time and for any reason revoke its consent upon written notice to Cardiotech

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With this letter, Cardiotech and Sub-Distributor seek Edwards' consent and ask that Edwards signs a copy of this letter to acknowledge and agree to this request. Once signed, Edwards shall return one original back to Cardiotech and one original to Sub-Distributor.

SOCIETATEA CARDIOTECH S.R.L. BUCUREȘTI-ROMÂNIA

Cardiotech S.R.L.

By: UNGUREANU MIHAELA

Title: ADMINISTRATOR

Date: 12/03/2020

Edwards Lifesciences SA

By: Adrian Braaman

Title: V.P. EMEA + CANADA

Date: 31.03.2020

Data Control SRL

By: ALEXANDRU GRABAZA

Title: GENERAL DIRECTOR

Date: 16/03/2020

DataControl

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:	*Arterial Cannula*
Classification:	*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 (MDD), 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. This Declaration of Conformity is supported by a valid MDD (Annex II.4) design examination certificate (2016183DE10), in combination with a valid Medical Device Regulation (2017/745 Annex IX) Quality Management System certificate (3828128CE01) covering similar devices. This declaration of conformity is endorsed by the approval of the Department for medical technology at the Health and Youth Care Inspectorate of the Ministry of Health, Welfare and Support in the Netherlands and is in line with the MDCG 2022-6 (MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR) recommendation. 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 per Certificate **3817373**, valid until 07 January 2024, and ISO 13485:2016 and EN ISO 13485:2016 per Certificate **3821948**, valid until 07 January 2024.

Notified Body:	*DEKRA Certification B.V* *Meander 1051* *6825 MJ Arnhem, The Netherlands* *Identification Number 0344*
EC Certificate:	*3828128CE01 (Annex IX, MDR)* *(Valid until 01 August 2027)* *2016183DE10 (Annex II.4, MDD)* *(Valid until 26 May 2024)*
Signed for and on behalf of Manufacturer:	*Edwards Lifesciences LLC* *Irvine, CA USA*

Ashwini Jacob
Vice President, Regulatory Affairs
Irvine, CA USA

Ashwini A. Jacob

Digitally signed by Ashwini A. Jacob
DN: cn=Ashwini A. Jacob, email=Ashwini_Jacob@edwards.com
Reason: I am approving this document
Date: 2023.01.05 14:05:15 -08'00'

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.
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

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

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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.
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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.

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