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

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 01.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.com, 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:

- MINIMALLY INVASIVE CARDIAC SURGERY CANNULAE

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.09.29 13:56:38 EEST
Reason: MoldSign Signature
Location: Moldova

Data 01.10.2023 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	

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, 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:

- MINIMALLY INVASIVE CARDIAC SURGERY CANNULAE

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 01.10.2023

LivaNova

Health innovation that matters

LETTER OF AUTHORIZATION

CARDIOPULMONARY PRODUCT LINE

September 20, 2023

To Whom It May Concern

We, **Sorin Group Italia S.r.l.**, a company with its registered address at Via Enrico Cialdini 16, 20161 Milano, Italy ("**LivaNova**"), is party to a certain non-exclusive distribution agreement effective as of January 1, 2023 (the "Agreement") with **Eximia Medical S.r.l.,** a company with its registered address at at Bucureşti Sectorul 2, Strada GHEORGHE ŢIŢEICA, Nr. 142, BIROU 1+15, Etaj 3, Romania ("**Distributor**"),whereby Distributor has a right to distribute and shall obtain and maintain all registrations, permits, licenses and approval necessary or appropriate for the importation and sales of the products in the territory of Romania and Republic of Moldova for the following LivaNova products:

- Heart Lung Machine with accessories and spare parts
- Autotransfusion Machine (XTRA) with accessories, spare parts and disposables
- Cardiopulmonary products and disposables
- Cannulae

This authorization is only valid until December 31, 2023 and for the avoidance of doubt, LivaNova reserves the right to revoke this authorization at any time without any restrictions and liability.

If there are any inquiries regarding this matter, please contact Vlado Klasic Sales Director Central East Europe, Adriatic, at e-mail: vlado.klasic@livanova.com and mobile: M +4179 930 28 11.

For and on behalf of **Sorin Group Italia S.r.l**

DocuSigned by:
Roberto Checchi
6514F73B0E6941F...

Roberto Checchi
Director

To: Whomever it may concern

Ref. Biosistem Mld SRL
Str. Albisoara Nr. 16/1 ap.7
Chisinau, R. Moldova

DISTRIBUTOR AUTHORIZATION

We, Eximia Medical S.R.L, a Romanian company, with its registered office address at Bucureşti, Sector 2, Strada GHEORGHE ŢIŢEICA, Nr. 142, BIROU 8, Etaj 4, Romania, authorized distributor (representative) for Romania and Moldova of Sorin Group Italia S.r.l., a company with its registered address at Via Enrico Cialdini 16, 20161 Milano, Italy ("LivaNova"), hereby confirm that:

Biosistem Mld SRL, a Moldavian company, with business office address at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, Phone: +373 22 808517; +373 22 808719; Fax. +373 22 808519, e-mail: biosistem.mld@gmail.com, IDNO (fiscal code) 1010600028048, VAT Code 0607490, bank account MD71PR0022241908460001840 USD, opened at ProCredit Bank S.A.. Chisinau Branch, SWIFT Code: PRCBMD22, legally represented by Poiata Vitalie as Administrator,

is authorized by us, to carry out the registration of products manufactured by Sorin Group Italia S.r.l. as they are mentioned in the annex to this authorization, in the records of the Ministry of Health of Republic of Moldova.

This authorization is valid from the date of its release until 31.12.2023.

EXIMIA MEDICAL S.R.L.
by Manager
Ungureanu Mihaela

13.07.2023

LivaNova

Health innovation that matters

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

We, LivaNova USA, Inc.
(supplier's name)

14401 West 65th Way, Arvada, CO 80004 USA
(supplier's address)

herewith holding the applicable product EC certificate, Annex II including (4), and current Quality System certificate confirming the company's establishment and maintenance of a quality system which meets the requirements of the standard(s) listed on the certificate

released by Notified Body: DEKRA Certification B.V., Arnhem, the Netherlands (CE0344), reference Certificate Number (3808732CE01)

declare under our sole responsibility that the product:

Name: **Minimally Invasive Cardiac Surgery (MICS) Bypass Cannula Kits, Cardiopulmonary Bypass Cannulae and Vascular Access Kits**

conforms to the provisions of the Medical Device Directive 93/42/EEC dated 14th June 1993, as amended (most recently by Directive 2007/47/EC).

Product designations appear on the following page(s).

This EC Declaration of Conformity is valid for two (2) years from the date of issue. It applies to all product lots released on or after the date of issue.

Place and Date of Issue: **Arvada, Colorado** **April 22, 2020**

Authorized Representative in the European Community
Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86
41037 Mirandola (MO) Italy
Telephone: 39-0535-29811
Fax: 39-0535-25229

Approved By LivaNova USA, Inc.:

Mattia Ronchetti, Director, Regulatory Affairs

April 22, 2020
Date

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LivaNova
Health innovation that matters

MINIMALLY INVASIVE CARDIAC SURGERY (MICS) CANNULAE (CLASS III)	3808732DE01

MINIMALLY INVASIVE CARDIAC SURGERY CANNULAE (CLASS III):			
CATALOG NO.	DESCRIPTION	SIZE	RULE
103-200	EasyFlow™ Aortic Cannula	19 Fr	7
103-210	EasyFlow™ Duo Cannula	19 Fr	7
103-210B	EasyFlow™ Duo Cannula	19 Fr	7
103-300	EasyFlow™ Aortic Cannula	23 Fr	7
103-310	EasyFlow™ Duo Cannula	23 Fr	7
200-100	Remote Access Perfusion (RAP) Femoral Venous Cannula	22 Fr	7
200-150	Remote Access Perfusion (RAP) Femoral Venous Cannula	23/25 Fr	7
200-200	FlexFlow™ Venous Cannula	23 Fr	7

EC CERTIFICATE

Number: **3808732CE01**

Full Quality Assurance System

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

Manufacturer:

LivaNova USA, Inc.

14401 West 65th Way
Arvada, CO 80004
United States Of America

For the product category(ies)

Minimally Invasive Cardiopulmonary Bypass Cannula Kits, Cardiopulmonary Bypass Cannulae and Vascular Access Kits

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 3808732CN, initially dated 20 December 2012
Addendum, initially dated 20 December 2012

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: **1 December 2023**
Issued for the first time: 20 December 2012
Revised: 24 March 2020
Reissued: 1 December 2018

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-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: **3808732CE01**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Minimally Invasive Cardiopulmonary Bypass Cannula Kits, Cardiopulmonary Bypass Cannulae and Vascular Access Kits

Issued to:

LivaNova USA, Inc.
14401 West 65th Way
Arvada, CO 80004
United States Of America

This certificate covers the following product(s):

- EasyFlow Aortic Cannula, 19-23 Fr (Class III)
- EasyFlow Duo Cannula, 19-23 Fr (Class III)
- FlexFlow Venous Cannula, 23 Fr (Class III)
- Remote Access Perfusion Femoral Venous Cannula, 22-25 Fr (Class III)
- Vascular Dilator Kit, 8-24 Fr (Class IIa)

Initial date: 20 December 2012
Revision date: 24 March 2020

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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