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. 4 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:

- NON-COATED AND PHOSPHORYLCHOLINE COATED SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS

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 13:57:09 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 deţin 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:

- NON-COATED AND PHOSPHORYLCHOLINE COATED SINGLE-USE CANNULAE FOR EXTRACORPOREAL CIRCUITS

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

DICHIARAZIONE DI CONFORMITÀ CE
EC Declaration of Conformity

La sottoscritta
We, the undersigned

Sorin Group Italia S.r.l.
v. Statale 12 Nord, 86
41037 Mirandola (MO) - Italia

con la supervisione dell'Organismo Designato
under the supervision of the Notified Body

DEKRA Certification B.V.-Identification no. 0344
Meander, 1051
6825 MJ Arnehem- The Netherlands

dichiara sotto la propria responsabilità che il prodotto
herewith declare under our sole responsability that the product

CANNULAE

NON-COATED AND PHOSPHORYLCHOLINE COATED SINGLE - USE CANNULAE FOR EXTRACORPOREAL CIRCUITS

realizzato nelle seguenti versioni
realized in the following models

VEDI ELENCO ALLEGATO (3 pagine)
see enclosed list (3 pages)

è in conformità con i requisiti della
is in compliance with the reference standard (s)

Direttiva 93/42/CEE del 14 giugno 1993 relativa ai dispositivi medici, Allegato II escluso (4),
recepita con Decreto Legislativo del 24/02/1997, n. 46 e succ. modifiche

MDD 93/42/EEC dated 14th June 1993 regarding Medical Devices, as amended by Directive 2007/47/EC, Annex II excluding (4), transposed by LD dated 24th February 1997, n°46 and further modifications.

Il Certificato di Sistema Completo di Garanzia di Qualità n° 2155862CE01 è stato rilasciato dall'Organismo Notificato il 28/02/2013 (riemesso in data 03 Marzo 2020)
Sorin Group Italia Quality System Conformity Certificate n° 2155862CE01 has been released by Notified Body on 28th February, 2013 (re-issued on 03rd March 2020).

Mirandola, lì 09/03/2020

Luigi Vecchi
Director, Regulatory Operations

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Sorin Group Italia S.r.l.

REF.	Name	CLASS
BP602-40	Coronary Perfusion Cannula 3D	IIa
BP602-50	Coronary Perfusion Cannula 3D	IIa
BP604-40	Coronary Perfusion Cannula 3D	IIa
BP604-50	Coronary Perfusion Cannula 3D	IIa
BP606-30	Coronary Perfusion Cannula	IIa
BP606-35	Coronary Perfusion Cannula	IIa
BP606-40	Coronary Perfusion Cannula	IIa
BP608-30	Coronary Perfusion Cannula	IIa
BP608-35	Coronary Perfusion Cannula	IIa
BP608-40	Coronary Perfusion Cannula	IIa
BP612-40	Coronary Perfusion Cannula 3D	IIa
BP612-50	Coronary Perfusion Cannula 3D	IIa
BP614-40	Coronary Perfusion Cannula 3D	IIa
BP614-50	Coronary Perfusion Cannula 3D	IIa
BP616-30	Coronary Perfusion Cannula	IIa
BP616-35	Coronary Perfusion Cannula	IIa
BP616-40	Coronary Perfusion Cannula	IIa
BP616-45	Coronary Perfusion Cannula	IIa
BP616-50	Coronary Perfusion Cannula	IIa
BP617-30	Coronary Perfusion Cannula	IIa
BP617-35	Coronary Perfusion Cannula	IIa
BP617-40	Coronary Perfusion Cannula	IIa
BP617-45	Coronary Perfusion Cannula	IIa
BP618-30	Coronary Perfusion Cannula	IIa
BP618-35	Coronary Perfusion Cannula	IIa
BP618-40	Coronary Perfusion Cannula	IIa
BP618-45	Coronary Perfusion Cannula	IIa
BP618-50	Coronary Perfusion Cannula	IIa
BR501-15	Aortic-Root Cannula	IIa
BR501-20	Aortic-Root Cannula	IIa
BR501-26	Aortic-Root Cannula	IIa
BR502-15	Aortic-Root Cannula	IIa
BR502-20	Aortic-Root Cannula	IIa
BR502-26	Aortic-Root Cannula	IIa
BR900-05	Aortic-Root Cannula	IIa
BR900-06	Aortic-Root Cannula	IIa
BR900-07	Aortic-Root Cannula	IIa

REF.	Name	CLASS
P602-40	Coronary Perfusion Cannula 3D	IIa
P602-50	Coronary Perfusion Cannula 3D	IIa
P604-40	Coronary Perfusion Cannula 3D	IIa
P604-50	Coronary Perfusion Cannula 3D	IIa
P606-30	Coronary Perfusion Cannula	IIa
P606-35	Coronary Perfusion Cannula	IIa
P606-40	Coronary Perfusion Cannula	IIa
P608-30	Coronary Perfusion Cannula	IIa
P608-35	Coronary Perfusion Cannula	IIa
P608-40	Coronary Perfusion Cannula	IIa
P612-40	Coronary Perfusion Cannula 3D	IIa
P612-50	Coronary Perfusion Cannula 3D	IIa
P614-40	Coronary Perfusion Cannula 3D	IIa
P614-50	Coronary Perfusion Cannula 3D	IIa
P616-30	Coronary Perfusion Cannula	IIa
P616-30/J	Coronary Perfusion Cannula	IIa
P616-30/NB	Coronary Perfusion Cannula	IIa
P616-35	Coronary Perfusion Cannula	IIa
P616-35/J	Coronary Perfusion Cannula	IIa
P616-40	Coronary Perfusion Cannula	IIa
P616-40/J	Coronary Perfusion Cannula	IIa
P616-45	Coronary Perfusion Cannula	IIa
P616-45/J	Coronary Perfusion Cannula	IIa
P616-50	Coronary Perfusion Cannula	IIa
P616-50/J	Coronary Perfusion Cannula	IIa
P617-30	Coronary Perfusion Cannula	IIa
P617-35	Coronary Perfusion Cannula	IIa
P617-40	Coronary Perfusion Cannula	IIa
P617-45	Coronary Perfusion Cannula	IIa
P618-30	Coronary Perfusion Cannula	IIa
P618-30/J	Coronary Perfusion Cannula	IIa
P618-30/NB	Coronary Perfusion Cannula	IIa
P618-35	Coronary Perfusion Cannula	IIa
P618-35/J	Coronary Perfusion Cannula	IIa
P618-40	Coronary Perfusion Cannula	IIa
P618-40/J	Coronary Perfusion Cannula	IIa
P618-45	Coronary Perfusion Cannula	IIa
P618-45/J	Coronary Perfusion Cannula	IIa
P618-50	Coronary Perfusion Cannula	IIa

REF.	Name	CLASS
P618-50/J	Coronary Perfusion Cannula	IIa
R501-15	Aortic-Root Cannula	IIa
R501-15/NB	Aortic-Root Cannula	IIa
R501-15/J	Aortic-Root Cannula	IIa
R501-20	Aortic-Root Cannula	IIa
R501-20/J	Aortic-Root Cannula	IIa
R501-26	Aortic-Root Cannula	IIa
R501-26/J	Aortic-Root Cannula	IIa
R502-15	Aortic-Root Cannula	IIa
R502-15/J	Aortic-Root Cannula	IIa
R502-15/NB	Aortic-Root Cannula	IIa
R502-20	Aortic-Root Cannula	IIa
R502-20/NB	Aortic-Root Cannula	IIa
R502-20/J	Aortic-Root Cannula	IIa
R502-26	Aortic-Root Cannula	IIa
R502-26/J	Aortic-Root Cannula	IIa
R900-05	Aortic-Root Cannula	IIa
R900-06	Aortic-Root Cannula	IIa
R900-07	Aortic-Root Cannula	IIa

EC CERTIFICATE

Number: 2155862CE01

Full Quality Assurance System

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

Manufacturer:

SORIN GROUP Italia S.r.l.

Via Statale 12 Nord, 86
41037 Mirandola (MO)
Italy

For the product category(ies)

Non-coated and phosphorylcholine coated single-use cannulae for extracorporeal circuits

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 2155862CN, initially dated 22 November 2012
Addendum, initially dated 28 February 2013

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: 26 May 2024
Issued for the first time: 28 February 2013
Reissued: 3 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

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: 2155862CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Non-coated and phosphorylcholine coated single-use cannulae for extracorporeal circuits

Issued to:

SORIN GROUP Italia S.r.l.
Via Statale 12 Nord, 86
41037 Mirandola (MO)
Italy

This certificate covers the following product(s):

Venous Cannulae (Class III)
- Venous Cannulae: PVC
- Venous Femoral Cannulae: PVC

Arterial Cannulae
- Aortic Cannulae: PVC (Class III)
- Arterial Femoral Cannulae: PVC (Class IIa)

Cardioplegia Cannulae (Class IIa)
- Cardioplegia Cannulae: PVC

Pediatric Cannulae (Class III)
- Venous Cannulae: PVC
- Arterial Cannulae: PVC

Vent Catheters (Class III)
- Vent Catheters: PVC

Initial date: 28 February 2013
Revision date: 5 September 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-product-safety.com Company registration 09085396