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. 5 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:

- DHF 02 HEMOCONCENTRATOR
- DHF 06 HEMOCONCENTRATOR

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 14:05:24 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:

- DHF 02 HEMOCONCENTRATOR
- DHF 06 HEMOCONCENTRATOR

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

TÜV PRODUCT SERVICE GMBH - Identification no. 0123
Ridlerstrasse, 65
80339 München - Germany

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

EMOCONCENTRATORI **EMOCONCENTRATORI PER PAZIENTI INFANTI-PEDIATRICI E ADULTI**

HEMOCONCENTRATORS ***INFANT/PAEDIATRIC AND ADULT HEMOCONCENTRATORS***

realizzato nelle seguenti versioni
realized in the following models

CODICE	DESCRIZIONE	CLASSIFICAZIONE
05009	D570 CONVENTIONAL ULTRAFILTRATION KIT DHF 02	IIa
05010	D571 CONVENTIONAL ULTRAFILTRATION KIT DHF 06	IIa
05019	D 575 MODIFIED ULTRAFILTRATION KIT DHF 02	IIa
05020	D 576 MODIFIED ULTRAFILTRATION KIT DHF 06	IIa
05326	DHF 02 HEMOCONCENTRATOR	IIa
05327	DHF 06 HEMOCONCENTRATOR	IIa
050179	SH14 HEMOCONCENTRATOR	IIa
050177	KH14 HEMOFILTRATION KIT	IIa

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° G1 057574 0070 è stato rilasciato dall'Organismo Notificato il 24/06/2019.
Sorin Group Italia Quality System Conformity Certificate n° G1 057574 0070 has been released by Notified Body on 24th June, 2019

Mirandola, lì 12/11/2019

L. Vecchi

DIRETTORE CP RA FRANCHISE
CP RA Franchise Director

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

Manufacturer:

Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86
41037 Mirandola MO
ITALY

Product Category(ies): **Disposable products for cardiopulmonary extracorporeal circulation (ECC), extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS); disposable products for blood processing, autotransfusion and blood monitoring systems. (as listed in the attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1292686

Valid from: 2019-06-24
Valid until: 2024-05-26

Date, 2019-06-24

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约
认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約
認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

Facility(ies): Sorin Group Italia S.r.l.
Via Statale 12 Nord, 86, 41037 Mirandola MO, ITALY

Attachment:

Product Families	Classification
DIDECO KIDS ARTERIAL FILTERS: Newborn- infant Arterial filters	IIa
DIDECO MICRO: Newborn- infant, Paediatric and Adult Arterial filters / bubble traps	IIa
VENOUS / CARDIOTOMY RESERVOIRS : Venous Cardiotomy reservoirs	IIa
DIDECO CARDIOPLEGIA SETS: Cardioplegia perfusion sets including also VANGUARD, DIDECO HELIOS and CSC14 Cardioplegia heat exchangers	IIa
CARDIOACCESSORIES/DIDECO CARDIOACCESSORIES: Auxiliary devices for cardiac surgery	IIa
HEMOCONCENTRATORS: Infant, paediatric and Adult Haemoconcentrators (DHF & SH models) and sets (KH & D models)	IIa
INSPIRE: adult and small adult oxygenators	IIa
DIDECO D905 EOS Paediatric and small adult oxygenators	IIa
SYNTHESIS: adult oxygenators including also VBT 8 venous bubble trap	IIa
DIDECO KIDS: new born- infant oxygenators	IIa
DIDECO LILLI PUT 1/LILLI PUT 2: newborn infant oxygenators	IIa
REVOLUTION: centrifugal pumps for extracorporeal circulation	IIa
PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxiliary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables).	IIa
DIDECO PERFUSION TUBING SYSTEMS: Perfusion tubing systems for cardiac surgery, ECMO and ECLS, including one or more main components (oxygenator, arterial filter, bubble trap, arterial line, venous line, pump boot tubing, centrifugal pump, hard or soft shell reservoir) feasibly connectable to auxiliary lines (secondary, cardioplegia or haemoconcentration sets, connectors or ancillary disposables,	IIa
DIDECO COLLECTION SYSTEMS: Autotransfusion collection systems, filters and accessories	IIa
BRAT 2: - Blood bags, collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags	IIb

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Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract
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On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
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In addition, for certificates with the right to use a certification mark and for QM certificates:
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维持证书有效性的原则要求：
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
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認証契約
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認証書の有効性に関する原則的な要求事項
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
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Requisitos para a validade do certificado (em princípio):
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
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(Devices in Class IIa, IIb or III)

No. G1 057574 0070 Rev. 00

- Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIa
BOWL: -Blood Bags and wash sets / autotransfusion sets including blood bags - Wash sets / autotransfusion sets without blood bags and accessories for autotransfusion	IIb IIa
ELECTA: - Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
XTRA: -Collection systems / disposable sets for autotransfusion, PPP, PRP, PLT gel including blood bags -Collection systems / disposable sets without blood bags and accessories for autotransfusion, PPP, PRP, PLT gel	IIb IIa
DIDECO DATA MASTER: Blood monitoring disposables connectors	IIa

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TÜV®

Zertifiziervertrag
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認証契約
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Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
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- Auditoria de monitoração realizada regularmente.