

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

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 3 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 și tipuri de dispozitive medicale
pentru introducerea și punerea la dispoziție pe piață a:

- S5/C5 Heart Lung Machine Systems

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de împuternicire

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	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău,
declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al
Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate
pentru notificarea dispozitivului medical:

- S5/C5 Heart Lung Machine Systems

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie

Semnătura _____

Data 01.10.2023



Health innovation that matters

LETTER OF AUTHORIZATION
CARDIOPULMONARY PRODUCT LINE

September 20, 2023

To Whom It May Concern

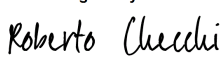
We, **Sorin Group Italia S.r.l.**, a company with its registered address at Via Enrico Cialdini 16, 20161 Milano, Italy ("**LivaNova**"), is party to a certain non-exclusive distribution agreement effective as of January 1, 2023 (the "Agreement") with **Eximia Medical S.r.l.**, a company with its registered address at at București Sectorul 2, Strada GHEORGHE ȚIȚEICA, 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:

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 București, Sector 2, Strada GHEORGHE ȚIȚEICA, 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



EG-Konformitätserklärung für Medizinprodukte
Declaration of Conformity for Medical Devices
(nach Anhang II der EG-Richtlinie über Medizinprodukte 93/42/EWG)
(according to annex II of the Council Directive 93/42/EEC concerning Medical Devices)

Name des Herstellers: LivaNova Deutschland GmbH
Name of Manufacturer:
Adresse des Herstellers: Lindberghstraße 25
Address of Manufacturer: 80939 München
Germany
Telefon/Phone: ++49 89 / 32301-0
Fax: ++49 89 / 32301-100

Wir erklären hiermit, dass das/die folgende(n) Medizinprodukt (e)
We herewith declare, that the following medical device(s)

Artikelnummer: <i>code number:</i>	Artikelbezeichnung: <i>designation:</i>	Klasse: <i>class:</i>
45-95-02	STÖCKERT S5	IIb
58-00-00	SORIN C5	IIb

den einschlägigen Bestimmungen der nachstehenden Richtlinie entspricht/entsprechen:
is/are in conformance with the Directive mentioned below:

Richtlinie 93/42/EWG über Medizinprodukte
Council Directive 93/42/EEC concerning Medical Devices

Für das/die o.g. Medizinprodukte wurde von unserer Benannten Stelle TÜV Product Service das EC Zertifikat
G1 098560 0001 Rev. 01 ausgestellt.

For the above mentioned medical device(s) our Notified Body has issued the EC Certificate G1 098560 0001 Rev. 01

Adresse/address: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, D-80339 München

Kennnummer/identification no.: 0123

Das/die o.g. Medizinprodukt(e) ist/sind ein modulares System, das aus optionalen Komponenten
bestehen kann, wie in der beigefügten Liste („Detachable Parts“) aufgeführt.

*The above mentioned medical device(s) is/are a modular system that can be composed of optional components, as
mentioned in the attached list of "Detachable Parts".*

Diese Konformitätserklärung gilt über die Laufzeit des o.g. EC Zertifikats.

This declaration of conformity is valid until the above mentioned EC certificate expires.

München, den 20. Mai 2019
Munich,


Julia E. Leslie
Director Regulatory Affairs / Cardiac Surgery
LivaNova Deutschland GmbH

LivaNova Deutschland GmbH
Lindberghstrasse 25
D-80939 München

T +49 (0)89 323 01 0
F +49 (0)89 323 01 100
www.livanova.com

Amtsgericht München
HRB 100852
USt-IdNr. (VAT): DE 129304291
Steuer-Nr: 143/157/71529

Geschäftsführer:
Cesare Antoniazzi
Jens Dreeßen
Alexander H.J. Neumann

Attachment to the Declaration of Conformity for S5 / C5 Heart Lung Machine Systems

List of detachable parts:

The item numbers listed below are optional components and detachable components of the S5 / C5 devices. Within the meaning of article 17 93/42/EEC, the CE mark may not be applied to each individual component for practicality reasons.

Rev: 051

Item Number	Description
16-05-40	S5 ice container
23-07-40	Bubble sensor 1/4" (6,35 mm)
23-07-45	Bubble sensor 1/2" (12,7 mm)
23-07-50	Bubble sensor 3/8" (9.56 mm)
24-10-51	Notebook shelf
16-05-60	S5 tubing guide holder
12-05-80	Mast adapter
24-10-90	Datapad II, DMS software and S5 interface module
12-05-00	Venous line clamp mast mounted
24-10-10	Holder for Datapad II
10-07-20	Tubing inserts 1/4" x 1/16", red
10-07-21	Tubing inserts 1/4" x 3/32" yellow
10-07-22	Tubing inserts 3/8" x 1/16" black
10-07-23	Tubing inserts 3/8" x 3/32", blue
10-07-24	Tubing inserts 1/2" x 1/16" silver
10-07-25	Tubing inserts 1/2" x 3/32", green
10-07-26	Tubing inserts 5/8" x 3/32" brown
10-07-27	Tubing inserts 1/8" x 1/16" violet
10-07-28	Tubing inserts 3/16" x 1/16" turquoise

Item Number	Description
10-61-72	Tubing clamp inserts for variolock (Large) blue
10-61-73	Tubing clamp inserts for variolock (small) red
10-61-91	clamp insert variolock cardioplegia (1:1)
10-61-92	clamp insert variolock cardioplegia (2:1)
10-61-93	clamp insert variolock cardioplegia (4:1)
10-64-05	Clamp insert 1/8" x 1/16" violet
10-64-10	Clamp insert 3/16" x 1/16" mint green
10-64-15	Clamp insert 1/4" x 1/16" red
10-64-25	Clamp insert 1/4" x 3/32" or 5/16" x 1/16" yellow
10-64-40	Clamp insert 3/8" x 1/16" or 5/16" x 3/32" black
10-64-50	Clamp insert 3/8" x 3/32" blue
10-64-55	Clamp insert 1/2" x 1/16" grey
10-64-65	Clamp insert 1/2" x 3/32" green
10-64-69	Clamp insert 1/2" x 1/8" orange
10-64-70	Cardioplegia clamp insert 3/16"x 1/16" (1:1)
10-64-71	Cardioplegia clamp insert 1/4" x 1/16" (1:1)
10-64-72	Cardioplegia clamp insert 3/16"x 1/16" (2:1)
10-64-74	Cardioplegia clamp insert 1/4" x 1/16" (2:1)
10-64-76	Cardioplegia clamp insert 1/4" x 1/16" (4:1)
10-64-78	Cardioplegia clamp insert 17/64" x 1/16" (8:1)
10-80-00	S5 rollerpump 150 /S5 RP150
10-81-30	Variolock tubing clamp module RP 150
10-81-35	Tubing clamp block RP 150
10-84-60	S5 shelf for roller pump 150
10-84-64	S5 shelf for 2 roller pumps 150
10-85-00	S5 double roller pump 85 /S5 DRP 85
10-86-55	clamp insert DRP 85 (tubing clamp block) 1/8" x 1/16" violet
10-86-56	clamp insert DRP 85 (tubing clamp block) 1/4" x 1/16" red
10-86-57	clamp insert DRP 85 (tubing clamp block) 1/4" x 3/32" yellow
10-86-58	clamp insert DRP 85 (tubing clamp block) 5/16" x 3/32" black
10-86-59	clamp insert DRP 85 (tubing clamp block) 3/16"x 1/16" mint green

Item Number	Description
10-86-60	S5 Tubing clamp RP85 3/32x1/16", grey
10-88-00	1 x mast roller pump 150
10-88-60	1 x mast roller pump 85
12-30-90/95	3-joint mast holder for venous line clamp
12-40-00	Venous line clamp remote control
12-80-00	Electrical venous occluder
12-80-10	Occluder (with mast holder)
13-30-95	3-joint mast holder for venous line clamp
19-03-00	holder for gas bottles and heat exchanger
20-30-20	Sensor module 4-channels temperature monitor
21-15-00	3 channel timer
22-20-20	Sensor module 2-channel pressure monitor
23-26-91	3 joint mast holder with fast clamp connectors for 2 sensors Length: 620 mm
23-26-96	3 joint mast holder with fast clamp connectors for 2 sensors Length: 420 mm
23-27-40	Level sensor
23-27-41	Adhesive sensor holder
23-27-60	Adhesive sensor holder
23-40-00	Sensor module level monitor
23-45-05	APC
23-45-20	Bubble detector sensor module consisting of bubble sensors with holders of different sizes: 23-45-00, 23-45-01, 23-45-02, 23-45-03, 23-45-10, 23-45-11, 23-45-12, 23-45-13
23-45-22	S5 Sensor module APC
24-00-82	Datapad II complete without Software
24-90-15	Holder card reader complete
24-90-40	Datapad II without Software
25-40-45	Gas blender system (10 l/min)
25-40-46	Gas blender system (5 l/min)
25-40-47	Gas blender system (2 l/min)
25-40-70	Console holder for gas blender
25-60-00	B-Care ₅

Item Number	Description
25-60-20	B-Care _s sensor module
25-60-30	Holder for measuring head
25-60-70	Flow measurement sensor module
27-80-20	Sensor module cardioplegia control
28-95-00	4 position S5 system panel with 4 display and control modules
28-95-01	5 position S5 system panel with 5 display and control modules
28-95-03	3 position S5 system panel with 3 display and control modules
28-95-04	6 position S5 system panel with 6 display and control modules
28-95-10	Display and control module
28-95-30	Blank module
28-95-70	Control unit
28-95-80	Control panel for mast roller pump 150/85
28-95-85	Control panel for 2 mast roller pump 85
28-98-xx	E/P pack
29-02-50	S5 interface module
31-15-01	Temperature probe
31-15-02	Temperature probe
31-15-03	Temperature probe
35-05-50	Halogen console lamp
35-05-70	LED console lamp
43-42-61	Cover for fast clamp connectors
43-70-00	AC outlet without shelf for S5/C5 EU plug 230 V
43-70-05	AC outlet without shelf for S5/C5 French plug 230 V
43-70-10	AC outlet without shelf for S5/C5 Swiss plug 230 V
43-70-50	mechanical adapter
45-11-03	cable external device
45-12-00	S3 to S5 adapter cable
45-12-02	connection cable
45-12-03	cable for connection to the S5/C5 System (including blocking ferrite)
45-12-08	cable external pumps
45-12-12	cable patient monitor

Item Number	Description
45-12-57	cable online analyzer
45-12-58	cable coagulation analyzer
45-12-61	cable online analyzer
45-12-62	cable online analyzer
45-12-63	cable online analyzer
45-12-64	cable patient monitor
45-12-65	cable patient monitor
45-12-66	cable patient monitor
45-12-67	cable coagulation analyzer
45-12-68	cable coagulation analyzer
45-12-69	cable patient monitor
45-12-70	cable external device
45-12-72	cable patient monitor
45-12-74	cable patient monitor
45-12-81	Cable for 24V connection to the S5/C5 System
48-04-00	Writing desk DIN A4
48-30-00	S5 console 3 position
48-30-50	Telescope mast with infusion rack
48-30-51	Telescope mast movable with infusion rack
48-30-57	Push bar (horizontal)
48-30-67	Push bar mast (vertical)
48-30-77	Horizontal mast 3 position
48-30-78	Horizontal mast 4 position
48-30-79	Horizontal mast 5 position
48-30-81	Crossbar for movable mast (horizontal) 3 position
48-30-82	Crossbar for movable mast (horizontal) 4 position
48-30-83	Crossbar for movable mast (horizontal) 5 position
48-31-10	S5 shelf without AC outlet strip
48-31-19	AC outlet with shelf for S5 (3 size Console)
48-31-20/25	S5 pump spacer
48-31-30	S5 plexiglass display protector

Item Number	Description
48-40-00	S5 console 4 position
48-41-10	S5 shelf without AC outlet strip
48-41-19	AC outlet with shelf for S5 (4 size Console)
48-41-20	S5 pump spacer
48-41-30	S5 plexiglass display protector
48-41-70	S5 drawer holder
48-50-00	S5 console 5 position
48-51-10	S5 shelf without AC outlet strip
48-51-19	AC outlet with shelf for S5 (5 size Console)
48-51-20	S5 pump spacer
48-51-30	S5 plexiglass display protector
50-45-00	S5 mast system extension
50-45-05	Swivel telescope mast with infusion rack and castor
50-45-10	Two swivel arms
50-45-15	Vertical mast (including 2 horizontal masts)
50-45-20	Transport locking arm
50-70-57	Holder for mast pump module
50-80-00	Mast roller pump system 150
50-80-60	Mast roller pump system 85
50-80-62	Mast roller pump system with 2 MRP 85 S5
50-80-63	Mast roller pump system with 2 MRP 85 C5
50-80-70	Mast roller pump system 85
50-80-99	Colour coding set
55-91-50	Mast holder with fast clamp connector
58-42-30	Side mast (left and/or right oriented)
59312/1	holder for thermo box (SA 13/19)
59312/3	EVO holder (SA 13/19)
60-00-50	SCP system
60-00-55 60-00-10	SCP Plus
60-00-60	CP5 centrifugal driver

Item Number	Description
60-01-00	SCP drive unit
60-01-04	CP5 drive unit
60-01-35	Emergency system
60-01-50	Emergency system
60-02-50	Pump control panel
60-02-60	Pump control panel
60-05-60	Electrical remote controlled tubing clamp
60-05-65	Electrical remote controlled tubing clamp
75-521-548	mast holder for level sensor
96-414-120	Flow sensor
96-415-126	Datapad II
97-231-059	Venous sensor
S20787/1	holder for mast (SA15/02)
S22940/1	special mast (SA15/02)
S24392/56	special cable (SA14/33)
S2549/25	additional mast (SA15/02)
S7265/3	special cable (SA13/25)
SA 47240-51	special holder
SA 47240-60	special holder
SA 64-896	AC outlet with special shelf for S5
SA 69379-1	special cable SCP panel EN block
SA 82303-01	special cable for SCPC (SA15/06)
SA14946/18	special cable (SA 13/24)
SA29001/1	S5 pump spacer(SA14/28)
SA42619-45	adapter plate (SA14/12) corresponds to SM000025 (SOR 2017-06)
SA47240-30	drawer special version (SA14/12)
SA47240-40	mast system special version (SA14/12)
SA47240-50	special mast (SA14/12)
SA47240-60	special holder pump unit (SA14/12)
SA47240-61	special holder corresponds to SM000029 (SOR 2017-04)
SA47240-70	panel special version (SA14/12)

Item Number	Description
SA47240-80	panel special version (SA14/12) corresponds to SM000030 (SOR2017-06)
SA47240-81	panel special version (SA14/12) corresponds to SM000015 (SOR2017-06)
SA49320	adapter (SA15/08)
SA49468-12	special holder length (SA15/20)
SA54992-10 special desk	special desk (SA14/12)
SA54992-14	special EVO clamp (SA14/12)
SA54992-67 special mast	special mast (SA14/12) corresponds to SM000013 (SOR2016-07)
SA55169-10	holder kit for mast double pump 85 (SA14/11) corresponds to SM000017 (SOR2017-06)
SA70764-10	special panel (SA14/11) corresponds to SM000016 (SOR2017-06)
SA70764-30	special adapter (SA14/14)
SA70872	special holder (SA72915/SA14/15)
SA73367	special mast (SA 14/20)
SA76547-1	special cable(SA14/25)
SA76547-2	special cable(SA14/25)
SA76758-10	special desk (SA14/26, 14/27)
SA76758-80	panel special version (SA14/26, 14/27)
SA76758-81	panel special version (SA14/26, 14/27)
SA77737-10	special Datapad holder (SA14/30)
SA85167-04	special holder length S5 MRP (SA15/14)
SA86817-10	special cable Heater Cooler (SA15/19) corresponds to 2017-11 SE-000003 + 2017-01
SA28582	special mast system (SA16/03)
SA89947-10	special cable for Flextherm (SA16/01)
SE000001	special cable DHZ S5 (SOR 2016-06)
SM000017	twin holder kit for MRP 85 (SOR 2016-07 Giessen)
SM000016	panel complete (SOR 2016-07 Giessen)
SM000015	panel DRP (SOR 2016-07 Giessen)
SM000009	drawer module (SOR 2016-07 Giessen)
SM000001	Bedienpult (SOR 2016-07 Giessen)
96-415-130	Datapad III
25-02-10	VAMOS Holder
SE000004	special cable Datex 4m (SOR2017-02)
SE000005	S5 special connection cable XTRA 6m (SOR2017-08)

Item Number	Description
35-05-80	LED console lamp
SM000020 SM000021 SM000027 SM000028	special cable guides for SOR 2017-18
48-35-00	S5 Min.l. (specific configuration of S5)
SE000008 SE000009	interface connection cable with special length 8,0 m (SOR2017-20)
SE000010	Special cable, length 8m (SOR 2017-22)
SE000011	Special cable, length 4m (SOR2017-24)
SE000007	Special connector with 3 serial lines (2017-15)
SM000035-46	Special components for S5 (SOR2017-12)
SM000047-48	S5 Mastsystem (SOR2018-02)
SE000003	Special cable for Heater Cooler 3T (SOR2018-05)
SM000031-34	S5 Special mast (SOR 2017-19)
SM000049-51	Special S5 telescope masts (SOR 2018-06)
SM000054 SM000055	CP5 panel in shelf (SOR 2018-11) nur 1 panel



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 098560 0001 Rev. 01

Manufacturer:

LivaNova Deutschland GmbH

Lindberghstr. 25
80939 München
GERMANY

Facility(ies):

LivaNova Deutschland GmbH
Lindberghstr. 25, 80939 München, GERMANY

Product Category(ies): Heart Lung Machine Systems,
Hypothermic Devices, Data Management
Systems for Cardiopulmonary Perfusion,
Gas and Bloodgas Management Systems,
Blood Processing and Autotransfusion
Systems

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.:

713153940

Valid from:

2019-05-20

Valid until:

2024-05-19

Date,

2019-05-20

Stefan Preiß