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 21.08.2023

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:

- Heart Valves / Sorin Mecharical Heart Valves

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

Data 21.08.2023 Semnătura _____

Tabelul de recepţionare 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	Accepted
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	Nr. 7232 din 21.08.2023
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Clavadelschi Dionisie
Semnătura persoanei responsabile	

Digitally signed by Poiata Vitalie
Date: 2023.09.29 16:31:35 EEST
Reason: MoldSign Signature
Location: Moldova

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

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. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Heart Valves / Sorin Mechanical Heart Valves

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 21.08.2023

November 17, 2022

Power of Attorney
(hereinafter the "Letter")

To whom it may concern,

This Letter confirms that **Corcym S.r.l.** with registered address at Centro Leoni, Via Giovanni Spadolini 7, 20141 Milano, Italy (hereinafter "Corcym") authorizes **SC Revismed Medical Srl**, a company with registered address at str. Traian Vuia, nr. 92, 400387 Cluj-Napoca, Romania (hereinafter "**SC Revismed Medical Srl**") and its local dealer **Biosistem-mld**, located at Albisoara 16/1 ap. 7, Chisinau, Republic of Moldova (sub-dealer of SC Revismed Medical Srl**)** a right to register, renew and update any relevant documentation, including but not limited to obtaining the Registration Certificate issued in the name of Corcym for the following medical products:

- Heart valves and accessories

within the territory of Moldova.

This Letter is valid until 31 December 2023 and for the avoidance of doubt Corcym reserves the right to revoke this Power of Attorney at any time without any restrictions and liability.

If there are any questions regarding this matter, please feel free to contact Corcym at alberto.minguzzi@corcym.com.

On behalf of Corcym S.r.l.

Adelina Chiaravalloti (Nov 17, 2022 13:44 GMT+1)

Adelina Chiaravalloti
Director, Clinical and Regulatory Affairs

CORCYM
WE TAKE LIFE TO HEART

DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

La sottoscritta **Corcym S.r.l.** (Via Crescentino sn, 13040 Saluggia, VC – Italia) dichiara sotto la propria responsabilità di Fabbricante che i prodotti sotto elencati sono conformi alle disposizioni applicabili della Direttiva del Consiglio 93/42/CEE e del Regolamento (UE) della Commissione no. 207/2012.

We, the undersigned ***Corcym S.r.l.*** *(Via Crescentino sn, 13040 Saluggia, VC – Italy) declare under our sole responsibility as Manufacturer that the products identified below conform to the relevant provisions of Council Directive 93/42/EEC and Commission Regulation (EU) no. 207/2012.*

Identificazione prodotto *Product identification*				
Prodotto *Product*	**Taglia** *Size*	**Codice prodotto (REF)** *Catalogue number (REF)*	**Codice d'ordine** *Ordering code*	**Classe** *Class*
Bicarbon Fitline LFA Aortic	19	ART19LFA	ICV0917	III
	21	ART21LFA	ICV0918	
	23	ART23LFA	ICV0919	
	25	ART25LFA	ICV0920	
	27	ART27LFA	ICV0921	
	29	ART29LFA	ICV0922	
	31	ART31LFA	ICV0923	
Bicarbon Fitline LFM Mitral	19	MTR19LFM	ICV0924	III
	21	MTR21LFM	ICV0925	
	23	MTR23LFM	ICV0926	
	25	MTR25LFM	ICV0927	
	27	MTR27LFM	ICV0928	
	29	MTR29LFM	ICV0929	
	31	MTR31LFM	ICV0930	
	33	MTR33LFM	ICV0931	
Bicarbon Slimline LSA Aortic	17	ART17LSA	ICV0934	III
	19	ART19LSA	ICV0935	
	21	ART21LSA	ICV0936	
	23	ART23LSA	ICV0937	
	25	ART25LSA	ICV0938	
	27	ART27LSA	ICV0939	
Bicarbon Overline Aortic	16	ART16LOV	ICV0870	III
	18	ART18LOV	ICV0871	
	20	ART20LOV	ICV0872	
	22	ART22LOV	ICV0873	
	24	ART24LOV	ICV0874	

CORCYM SRL
Sede Legale
Via Benigno Crespi 17 – 20159 Milano – Italy

Sede Amministrativa
Via Benigno Crespi 17 – 20159 Milano – Italy
Via per Crescentino sn – 13040 Saluggia (VC) Italy
Tel.+39 0161 487.1 – Fax +39 0161 487.545

Stabilimento
Via Crescentino sn – 13040 Saluggia (VC) Italy

PEC: CORCYM@LEGALMAIL.IT

Capitale Sociale: € 2.000.000,00
R.E.A. MILANO 2608814
Registro Imprese di Milano N.11515960968
Cod. Fiscale / Part. IVA 11515960968

ISO Code: IT11515960968
corcym.com

Informazioni relative alla valutazione della conformità *Conformity assessment information*		
Organismo Notificato ***Notified Body***	**Procedura di valutazione conformità** ***Conformity assessment procedure***	**Numero certificati CE** ***CE Certificates number***
TÜV SÜD Product Service GmbH (0123) Ridlerstr. 65, D-80339 München, GERMANY	Dichiarazione di Conformità CE di cui all' Allegato II, Direttiva 93/42/CEE (Sistema completo di assicurazione di qualità) *EC Declaration of Conformity set out in Annex II, Directive 93/42/EEC (Full Quality Assurance)*	- Annex II section 4: G7 001664 0034 Rev. 01 Valid until: 2024-05-26 - Annex II excluding section 4: G1 001664 0038 Rev.01 Valid until: 2024-05-26

La presente Dichiarazione di Conformità è valida per i dispositivi prodotti presso l'officina sita in Via Crescentino sn, 13040 Saluggia, VC – Italia e descritti nel Technical File TF-08.

This Declaration of Conformity is valid for the medical devices manufactured in the facility of Via Crescentino sn, 13040 Saluggia, VC – Italy and described in the Technical File TF-08.

La presente Dichiarazione di Conformità è valida a partire dalla data di firma e fino alla prima data di scadenza dei certificati sopra indicati.

This Declaration of Conformity is valid from the signature date until the earliest expiry date of the certificates identified above.

Saluggia, June 1st, 2021

Adelina Chiaravalloti

Director, Regulatory Affairs and Clinical Evaluation
Corcym S.r.l.

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

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

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 001664 0034 Rev. 01

Manufacturer:

Corcym S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product:

Heart Valves
Sorin Mechanical Heart Valves

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G7 001664 0034 Rev. 01

Report no.: 713206835

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-10

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 001664 0034 Rev. 01

Model(s):

Bicarbon Fitline
Bicarbon Slimline
Bicarbon Overline

Parameters:

Model Name	Product codes
Bicarbon Fitline LFA Aortic	ICV0917/ART19LFA
	ICV0918/ART21LFA
	ICV0919/ART23LFA
	ICV0920/ART25LFA
	ICV0921/ART27LFA
	ICV0922/ART29LFA
	ICV0923/ART31LFA
Bicarbon Fitline LFM Mitral	ICV0924/MTR19LFM
	ICV0925/MTR21LFM
	ICV0926/MTR23LFM
	ICV0927/MTR25LFM
	ICV0928/MTR27LFM
	ICV0929/MTR29LFM
	ICV0930/MTR31LFM
	ICV0931/MTR33LFM
Bicarbon Slimline LSA Aortic	ICV0934/ART17LSA
	ICV0935/ART19LSA
	ICV0936/ART21LSA
	ICV0937/ART23LSA
	ICV0938/ART25LSA
	ICV0939/ART27LSA
Bicarbon Overline Aortic	ICV0870/ART16LOV
	ICV0871/ART18LOV
	ICV0872/ART20LOV
	ICV0873/ART22LOV
	ICV0874/ART24LOV

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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 001664 0038 Rev. 01

Manufacturer:

Corcym S.r.l.
Via Crescentino sn
13040 Saluggia (VC)
ITALY

Product Category(ies): **Mechanical Heart Valves**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 001664 0038 Rev. 01

Report No.: ITA1663134

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-10

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®