Digitally signed by Poiata Vitalie
Date: 2025.02.13 12:39:41 EET
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531522** data **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**
Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociaţii:
1. POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%
Beneficiar efectiv:
1.1. POIATA VITALIE, IDNP 0983103892591,

2. NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
2.1. NASEDCHIN ALEXANDR, IDNP 2002001070747,

3. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
3.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **15.09.2023**.

Registrator în domeniul înregistrării de stat

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova

Rusu Diana

EB 0461494

Date cu caracter personal

BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

CERTIFICATE

EC Certificate No. 1434-MDD-352/2020
Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi-396191
Gujarat, India

for the design, manufacture and final inspection of
medical devices, class III

Pericardial Bioprosthesis

Brand names: Dafodil, Dafodil Neo, Flomero, Freesia

The list of medical devices covered by this certificate is provided in the annex 1 to EC Design examination Certificate No. 1434-MDD-351/2020

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2020-10-09 to 2024-05-27

The date of issue of the Certificate: 2020-10-09

The date of the first issue of the Certificate: 2019-10-09

CE 1434

Issued under the Contract No. **MD-73/2018**
Application No: 268/2020
Certificate bears the qualified signature.
Warsaw, 09/10/2020
Module H2/3/4/5

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.06 17:34:17 +02'00'

Anna Wyroba
Vice-President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Meril

DECLARATION OF CONFORMITY

Manufacturer's Name: **MERIL LIFE SCIENCES PVT. LTD.**

Manufacturer's Address: Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.

Product Name: **Dafodil™ - Pericardial Bioprosthesis**

Product Details:

GMDN Code	P 60242 & 60244	Control No.:RO/DOC/DDL/Rev.00
Batch No.:	_____	Mfg. Date: _____
Batch Released Quantity::	_____	Expiry Date: _____

Conforms to the applicable national/ international Standards.

(List of UDI -DI covered by this declaration are enlisted in the Annexure -I)

1. We declare that our products as listed below, comply with the requirements to Medical device Directive 93/42/EEC as amended by directive 2007/47/EC, Commission Regulation (EU) No. 722/2012 of 8 August 2012, Annex I and this declaration is sole responsibility of company.

A. **Dafodil™ Pericardial Bioprosthesis.**

- **Dafodil™ Pericardial Bioprosthesis (Aortic):**
  An Aortic Dafodil™ Pericardial Bioprosthesis is indicated for use in patients whose aortic valvular disease is sufficiently advanced to warrant replacement of their natural valve with a prosthetic one. It is also intended for use in patients with a previously implanted aortic valve prosthesis which is no longer functioning adequately and requires replacement. In the latter case, the previously implanted prosthesis is surgically excised and replaced by the replacement prosthesis.
- **Dafodil™ Pericardial Bioprosthesis (Mitral):**
  The Mitral Dafodil™ Pericardial Bioprosthesis is indicated for use in patients whose mitral valvular disease is sufficiently advanced to warrant replacement of their natural valve with a prosthetic one. It is also intended for use in patients with a previously implanted mitral valve prosthesis which is no longer functioning adequately and requires replacement. In the latter case, the previously implanted prosthesis is surgically excised and replaced by the replacement prosthesis.
- **Dafodil™ Aortic/Mitral Sizer Set:** A sizer assembly is provided for determining appropriate size of the prosthesis to suit the implant site anatomy. A handle is provided to hold the bioprosthesis during the procedure.

2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per ISO 13485:2016/NS-EN ISO 13485:2016.
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and competent Authority for a period ending 15 (Fifteen) years after the last product has been manufactured.
5. Company or his authorized representative shall fulfill the obligations imposed by Annex II (Full Quality Assurance system) of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.
8. Company shall fulfill the obligations imposed by Annex I of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
9. Company declares that Dafodil™ Pericardial Bioprosthesis contains material of animal tissue derivative.

List of Standard Applied:	EN ISO 13485:2016/AC:2016, EN ISO 14971:2012, IEC 62366-1:2015, EN ISO 15223-1:2016, EN ISO 1041:2008 +A1 2013, EN ISO 10993-1:2018/AC 2010, EN ISO 11607-1:2017, EN ISO 11607-2: 2017, EN ISO 11737-1:2006, ISO 11135-1:2014, EN ISO 22442-1:2015, EN ISO 22442-2:2015, EN ISO 2242-3:2007, EN ISO 80369-7:2017, EN ISO 14155:2011, ASTM F 1980:2016, MDD 93/42/EEC/1993, Directive 2007-47-EC, MDD 2001/83/EC, 6th Nov 2001 as amended by 2012/26/EU, MEDDEV 2.1/3, December 2009, MEDDEV 2.4/1 Rev.9, June 2010, MEDDEV 2.7/1, Rev . 4 June 2016 & Appendix 1, ICH Harmonized Tripartite Guidelines Q1A(R2) February 2003.
Conformity Assessment Route:	Annex: II. of MDD/93/42/EEC on Medical Devices as amended.
Device Classification:	Dafodil™ Pericardial Bioprosthesis is a surgically invasive long term use and implantable device used in direct contact with heart and incorporates animal tissue derivative, hence it is classified as "Class III" medical device as per Annexure IX, Rule 8 and Rule 17 of MDD/93/42/EEC, 14th June 1993 as amended by 2007/47/EC.
Certificate No.:	EC Certificate No.: 1434-MDD-352/2020 EC Design certificate No.: 1434-MDD-351/2020
Certificate Issue Date:	2020-10-09
Certificate Valid till:	2024-05-27
European Authorized Representative:	Obelis s.a., Bd. General Wahis 53,1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Notifying Body:	Polskie Centrum Badan i Certyfikacji S.A.z siedziba w Warszawie (Polish Centre for Testing and Certification PCBC) ul. Pulawska 469, 02-844 Warszawa, Poland Website: www.pcbc.gov.pl Phone: **+48 22 46 45 200** Fax: **+48 22 46 45 251**
Notifying Body No.:	1434

Signature:

Meril Life Sciences PVT. LTD. Vapi

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD IDNO 1016600028048 REPUBLICA MOLDOVA

Name: Mr. Pratik Vasani
Designation: AGM - Regulatory Affairs
Date/Location: **Date**: 05.11.2022 **Location**: Vapi, Gujarat, INDIA

CE 1434

Annexure I - List of UDI -DI for Dafodil™ Pericardial Bioprosthesis (Aortic and Mitral)

Sr. No.	Product Name	UDI -DI
1.	Dafodil™ Pericardial Bioprosthesis (Aortic and Mitral)	89042249PBE8

CE
1434

CERTIFICATE

EC Certificate No. 1434-MDD-351/2020

EC Design-examination
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi-396191
Gujarat, India

related to the medical device, class III

Pericardial Bioprosthesis

Brand names: Dafodil, Dafodil Neo, Flomero, Freesia

The list of medical devices covered by this certificate is provided in the annex 1

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2020-10-09 to 2024-05-27

The date of issue of the Certificate: 2020-10-09

The date of the first issue of the Certificate: 2019-10-09

CE 1434

Issued under the Contract No. **MD-73/2018**
Application No: 268/2020
Certificate bears the qualified signature.
Warsaw, 09/10/2020
Module H1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.06 17:33:28 +02'00'

Anna Wyroba
Vice-President

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-351/2020

List of medical devices covered by the certificate:

1. Product name:
   Generic name :Pericardial Bioprosthesis
   Brand names: Dafodil™ Pericardial Bioprosthesis
   Dafodil Neo™ Pericardial Bioprosthesis
   Flomero™ Pericardial Bioprosthesis
   Freesia™ Pericardial Bioprosthesis
2. GMDN Code: 60242 & 60244
3. Product Description: The Pericardial Bioprosthesis is comprised of three leaflets made from bovine pericardial tissue, a frame and a sewing ring. A sizer assembly is provided for determining appropriate size of the prosthesis to suit the implant site anatomy. A Handle is provided to hold the bioprosthesis during the procedure.
4. Model/Variant
   a. **Model Numbers of Dafodil™ Pericardial Bioprosthesis**

Model	Reference / Catalogue Number				
	Available Bioprosthesis diameters (mm)	Dafodil™ Pericardial Bioprosthesis	Dafodil Neo™ Pericardial Bioprosthesis	Flomero™ Pericardial Bioprosthesis	Freesia™ Pericardial Bioprosthesis
Aortic Model	19	DDL19A	DDLN19A	FLOM19A	FRS19A
	21	DDL21A	DDLN21A	FLOM21A	FRS21A
	23	DDL23A	DDLN23A	FLOM23A	FRS23A
	25	DDL25A	DDLN25A	FLOM25A	FRS25A
	27	DDL27A	DDLN27A	FLOM27A	FRS27A
Mitral Model	23	DDL23M	DDLN23M	FLOM23M	FRS23M
	25	DDL25M	DDLN25M	FLOM25M	FRS25M
	27	DDL27M	DDLN27M	FLOM27M	FRS27M
	29	DDL29M	DDLN29M	FLOM29M	FRS29M
	31	DDL31M	DDLN31M	FLOM31M	FRS31M

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MD IDNO 1010600028048 REPUBLICA MOLDOVA

b. Model Numbers of Dafodil™ Pericardial Bioprosthesis Sizer Set*

Available Sizer Set	Reference / Catalogue Number
AORTIC SIZER SET	DFA1927
MITRAL SIZER SET	DFM2331

*Note: Dafodil™ Pericardial Bioprosthesis Sizer Set is compatible with additional brand names, Dafodil™ Neo Pericardial Bioprosthesis, Flomero™ Pericardial Bioprosthesis and Freesia™ Pericardial Bioprosthesis also.

CE 1434

Issued under the Contract No. **MD-73/2018**
Application No: 268/2020
Certificate bears the qualified signature.
Warsaw, 09/10/2020

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.06 17:32:04 +02'00'

Anna Wyroba
Vice-President