

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*

*L. Svirepova*  
semnătura

MD 0101250





## AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților 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 și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei.**

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

Asociații:

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 și a întreprinzătorilor individuali și 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**



# 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: MOLDM2X329

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: MOLDM2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent  
in moneda nationala al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu  
**IBAN MD95ML000000002251429243.**

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

Ex. Diana Brinza  
Tel. 43-45-96

## **Lista fondatorilor Biosistem-mld SRL**

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



# 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**

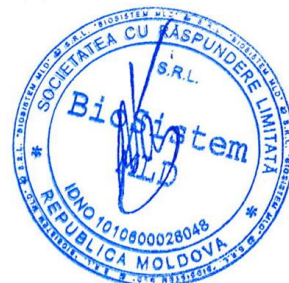
*The list of medical devices covered by this certificate is provided in the annex 1 to EC Design  
examination Certificate No. 1434-MDD-351/2020*

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

**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 &amp; 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 22442-3:2007, 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, 6<sup>th</sup> 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, 14<sup>th</sup> June 1993 as amended by 2007/47/EC.

**Certificate No.:** EC Certificate No.: 1434-MDD-352/2020

**Certificate Issue Date:** EC Design certificate No.: 1434-MDD-351/2020

**Certificate Valid till:** 2020-10-09

**European Authorized Representative:** 2024-05-27

Obelis s.a.,

Bd. General Wahis 53,1030 Brussels, Belgium

**Notifying Body:** Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: [mail@obelis.net](mailto:mail@obelis.net)

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

**Notifying Body No.:** Website: [www.pcbc.gov.pl](http://www.pcbc.gov.pl) Phone: +48 22 46 45 200 Fax: +48 22 46 45 251

1434

**Signature:**

**Name:**

**Designation:**

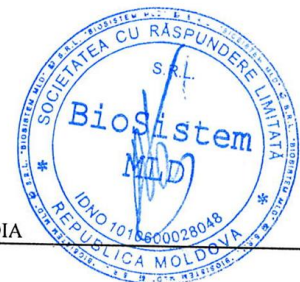
**Date/Location:**

Mr. Pratik Vasani

AGM - Regulatory Affairs

Date: 05.11.2022

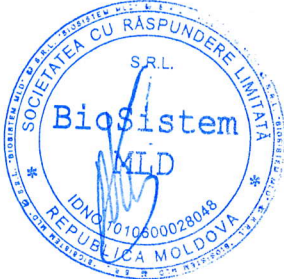
Location: Vapi, Gujarat, INDIA





**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





# 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

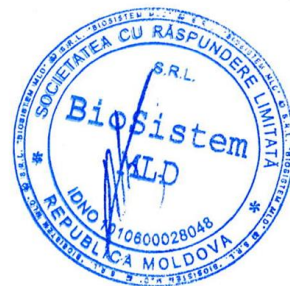
The date of the first issue of the Certificate: 2019-10-09

**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

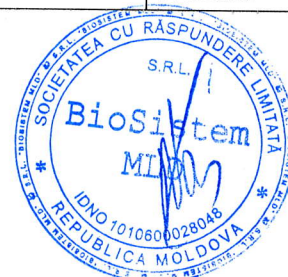
2. GMDN Code: 60242 & 60244

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

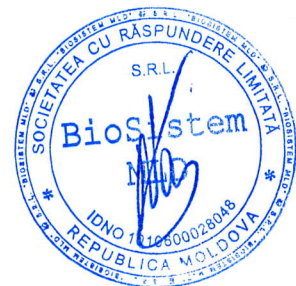




**b. Model Numbers of Dafodil™ Pericardial Bioprosthesis Sizer Set\***

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