

## Date generale despre ofertant

<b>SRL Biosistem mld</b>
<b>Administrator:</b> Poiata Vitalie
<b>Adresa poștală:</b> str. Albișoara 16/1 of.7, or. Chișinău
<b>Tel./Fax:</b> .+373-22-808517, +373-22-808719, fax +373-22-808519
<b>E-mail:</b> biosistem.mld@gmail.com; info@biosistem-mld.com
<b>Cod IBAN:</b> MD95ML000000002251429243
<b>Banca:</b> BC "Moldindconbank" S.A. fil. Invest
<b>Codul băncii:</b> MOLDMD2X329
<b>Cod fiscal:</b> 1010600028048
<b>Cod TVA:</b> 0607490

Cu respect,

Vitalie Poiata

Administrator



# 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 Balmuş

Ex. Diana Brinza  
Tel. 43-45-96

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**

## **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>



# DECLARATION OF CONFORMITY

## ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer

### EU Representative

**SUNGO Europe B.V.**  
**Fascinatio Boulevard 522, Unit 1.7,**  
**2909VA Capelle aan den IJssel,**  
**The Netherland**  
**SRN: NL-AR-000000247**

### Conformity Assessment

**Conformity Assessment Procedure**  
Annex II+III of Regulation (EU) 2017/745

#### Applicable Standards

EN ISO 14971: 2019,  
EN 1041:2008+A1 2013,  
EN ISO 15223-1: 2021  
ISO 10993:2018  
ISO 10993-5:2009  
ISO 10993-10:2010  
IEC 60601-1:2005+AMD1:2012+AMD2:2020  
CSV  
IEC 60601-1-2:2014+AMD1:2020 CSV  
IEC 60417:2012  
IEC 60601-1-11:2015

#### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-RFVB-01.*  
*All the supporting documentation is retained at the premises of the manufacturer.*  
*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

### Manufacturer

**Name:** Guangdong Yuehua Medical Instrument Factory Co., Ltd.

**Address:** Rongsheng Science and Technology Zone, Daxue Road, Shantou, Guangdong, China

**SRN:** CN-MF-000004539

### Product Information

**Name:** Alternation Pressure Mattresses

#### Model:

QDC-303, P4000IIE(B), QDC-303+P4000IIE(B),  
QDC-300B, P4000IIE(C), QDC-300B+P4000IIE(C),  
QDC-5010E+P3000N2EB, QDC-8010+P3000A2QB3,  
QDC-8080+P3000A2QB3

**GMDN:** 63641

**Basic UDI-DI:** 694474954001M4, 694474954005MC,  
694474950030LF, 694474954004MA, 694474954006ME,  
694474950047LY, 694474950082M2, 694474950053LT,  
694474950055LX

**Classification:** Class I

### Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Name: HONG, LIN

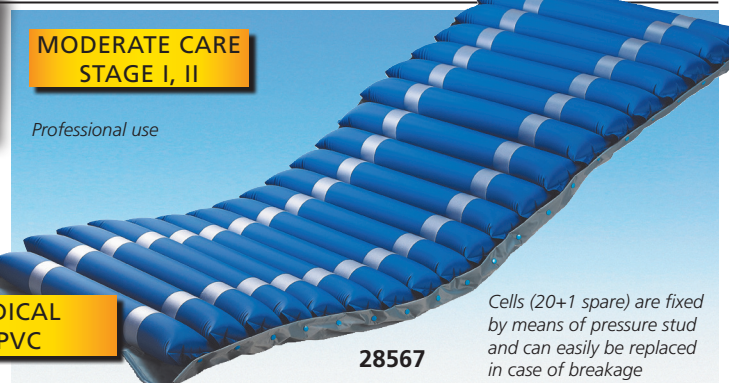
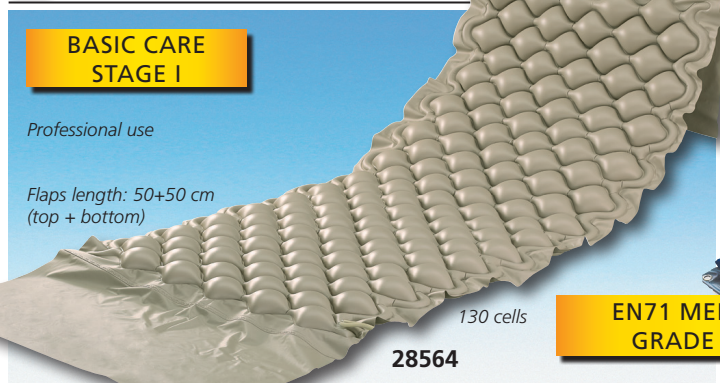
Position: GM

Date: 2022.10.18



Place: Guangdong/China

# ANTI-DECUBITUS AIR MATTRESSES WITH PUMP - STAGE I AND II



**BASIC CARE STAGE I**  
Professional use  
Flaps length: 50x50 cm (top + bottom)  
130 cells  
**EN71 MEDICAL GRADE PVC**  
**28564**

**ALTERNATING BUBBLE MATTRESS**  
Designed for the treatment and prevention of pressure sore stage I in short-term and domiciliary therapies. The PVC mattress is composed of 130 7 cm-high bubble cells, particularly comfortable. Fixable to bed by extra flaps on both top and bottom side. Cold-resistant -30 degrees.

**PUMP SYSTEM**  
Special silent pump for an excellent pressure regulation by a knob on the front panel. It can be hung to any kind of hospital bed frame by means of two adjustable hooks. For use with bubble or alternating cell mattresses. **28565**

**MODERATE CARE STAGE I, II**  
Professional use  
Cells (20+1 spare) are fixed by means of pressure stud and can easily be replaced in case of breakage  
**28567**

**ALTERNATING INTERCHANGEABLE CELL-MATTRESS**  
Recommended for the prevention and treatment of pressure sore stage I and II in medium-term and domiciliary therapies. The 20.5 cm-high Nylon+PVC cells provide superior comfort.

GIMA code	MATTRESSES AND PUMP
28564	Bubble mattress
28565	Pump for 28564
28566	Kit bubble mattress+pump (28564+28565)
28567	Interchangeable cell mattress
28568	Pump for 28567
28569	Kit cell mattress+pump (28567+28568)
28570	Spare cell for 28567

Manual and box in 10 languages: GB, FR, IT, ES, DE, PT, PL, HU, GR, Arabic

**TECHNICAL SPECIFICATIONS - PUMP**

	28565	28568
Size:	25x12x10 cm	
Operating voltage:	110-220 V, 50-60 Hz	
Working pressure:	40-100 mmHg	40-110 mmHg
Air output:	6-7 liter/min	6-7 liter/min
Cycle time:	6 min	12 min
Case:	TUV-CE IEC/EN60601-1; 60601-1-2	

**TECHNICAL SPECIFICATIONS - MATTRESS**

	28564	28567
Total size:	200x90x7 cm	200x86x9.5 cm
Cell height:	7 cm (2.7")	9.5 cm (4")
Material:	PVC	Nylon+PVC
Thickness:	0.32 mm	0.32 mm
Load:	135 kg	140 kg

# THERAPEUTIC ANTI-DECUBITUS MATTRESSES - STAGE III AND IV



**MODERATE TO INTENSIVE CARE STAGE I, II, III**  
Ventilated low-air-loss cells wicks moisture away  
Professional use  
Nylon PU cover with button biocompatibility, vapor permeable & water resistant with CA117. Flame Retardant Level.  
**28575**

• **28575 KIT 5010E ALTERNATING PRESSURE MATTRESS + PUMP**  
Valuable overlay system designed for prevention and treatment of patients at moderate to intensive risk of pressure ulcers. Pressure is periodically redistributed by inflating and deflating cells in order to mimic natural sleep movement patterns and avoid long term pressurization of tissue. Manual in: GB, FR, IT, ES, PT, DE, PL, RO, SE, GR.

• **28576 CELL for 28575 - spare**

**ALTERNATING FUNCTION**  
The pump inflates and deflates the cells with cyclicity (Group A and Group B as shown in the picture), to change the contact position between the patient and the bed, to promote the blood circulation, to prevent and recover the bedsore, reducing the patient's pain and the nursing labor. Pillow function (28580-2 only): the cells of the head position (Group C) don't alternate, for more comfort to the patient.

**INTENSIVE CARE STAGE I, II, III, IV**  
Cotton lining with zipper  
Professional use  
CPR straps quickly deflate the mattress for emergencies  
Low pressure alarm  
Air pressure dial adjustment  
**28580-2**

• **28580 KIT 8010 ALTERNATING PRESSURE MATTRESS + PUMP**  
• **28582 KIT 8080 ALTERNATING PRESSURE MATTRESS + PUMP**  
Advanced systems of alternating pressure mattresses. The multi-mode pump offers:  
- **alternating mode:** the pressure is periodically redistributed by inflating and deflating cells in order to mimic natural sleep movement patterns and avoid long term pressurization of tissue.  
- **constant static mode:** the pressure is about 2/3 lowered when compared to the same pressure level from alternating mode by means of immersion and envelopment. Visual alarms notify the caregiver of unusual situation, reducing the risk of human error. Suitable for the prevention and treatment of all stages of pressure ulcers. Manual in: GB, FR, IT, ES, PT, DE, PL, RO, SE, GR.

• **28581 CELL for 28580 - spare** • **28583 CELL for 28582 - spare**

**TECHNICAL SPECIFICATIONS - PUMPS (28575, 28580, 28582)**

Size:	30x13.5x11 cm	Cycle time:	12 min
Operating voltage:	220-240 V, 50 Hz	Working pressure:	55-120 mmHg
Case material:	Flame retardant ABS	Air output:	7-8 liter/min
	TUV-CE IEC/EN60601-1; 60601-1-2		

**PUMP 28580, 28582 only**  
Quick connector with transfer cap to transform mattress into a sealed static surface to facilitate patient transportation.

Quick connector

**TECHNICAL SPECIFICATIONS - MATTRESS**

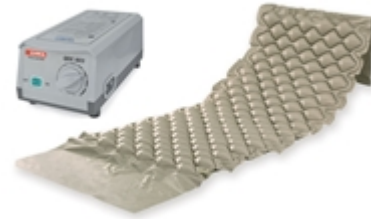
	28575	28580	28582
Total size:	198x86x12.8 cm	200x86x21 cm	
Alternating	1 in 2 (group A and B)		
Cell height:	12.8 cm (5")	20 cm (8")	
Cover material:	Nylon PU with button	Nylon+PU with cotton lining	
Thickness:	0.4 mm	0.4 mm	0.25 mm
Number of cells:	17+1 spare	20+1 spare	
Cells material:	nylon PVC	nylon PVC	nylon TPU
Load:	150 kg	160 kg	200 kg



# GIMA

## BUBBLE AIR MATTRESS + COMPRESSOR (28564+28565)

**Code:** 28566  
**Category:** Intensive care anti-decubitus mattresses  
**Unit of sale:** 1 kit  
**Minimum order:** 1  
**Type:** Medical device  
**Class:** I  
**NSIS:** 2398249  
**CND:** V080701  
**EAN13:** 8023279285666



**Description:**

- **BUBBLE MATTRESS**  
Designed for the treatment and prevention of pressure sore stage I in short-term and domiciliary therapies. The PVC mattress is composed of 130 7 cm-high bubble cells, particularly comfortable. Fixable to bed by extra flaps on both top and bottom side. Cold-resistant -30 degrees.  
Flaps length: 50+50 cm (top + bottom).

- **PUMP SYSTEM**  
Special silent pump for an excellent pressure regulation by a knob on the front panel. It can be hung to any kind of hospital bed frame by means of two adjustable hooks. For use with bubble or alternating cell mattresses.

**Technical Specifications:**

**Bubble mattress:**

- Total size: 200 x 90 x 7 cm
- Cell height: 7 cm (2.7")
- Material: PVC
- Thickness: 0.32 mm
- Number of cells: 130
- Suitable for persons up to: 135 kg

**Pump system:**

- Size: 25 x 12 x h 10 cm
- Operating voltage: 220 V, 50 Hz
- Working pressure: 40-100 mmHg
- Air output: 6-7 liter/min
- Cycle time: 6 min
- Plastic casing: Taiwan chimei ABS
- TUV-CE IEC/EN60601-1; 60601-1-2