

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



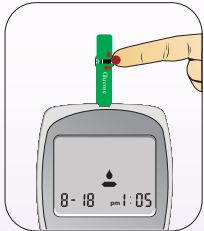
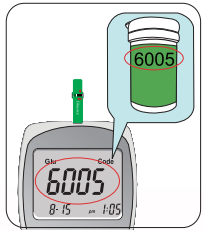
Nina Balmuș

Ex. Diana Brinza
Tel. 43-45-96

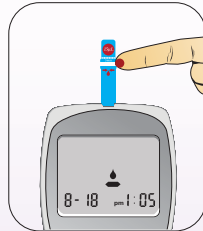
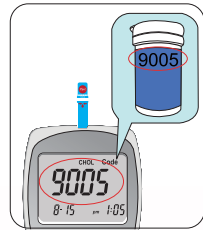
Lista fondatorilor Biosistem-mld SRL

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

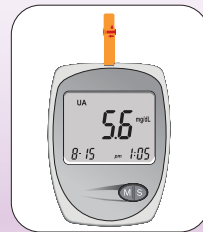
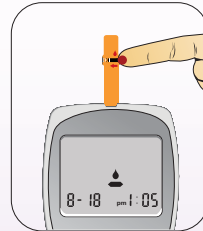
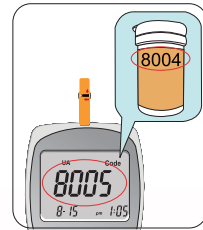
Glucose



Cholesterol



Uric Acid

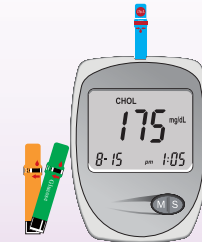


EasyTouch® – watching over your health

EasyTouch® GCU

Blood Glucose / Cholesterol / Uric Acid Multi-Function Monitoring System

Meter Identifies The Strips Automatically
Result in 10 Seconds (Glucose) / 20 Seconds (Uric Acid) / 150 Seconds (Cholesterol)
200 Glucose / 50 Cholesterol / 50 Uric Acid Test Results
Memory 7 . 14 . 28 Days Glucose Test Averaging
Auto Power ON & OFF



3 in 1

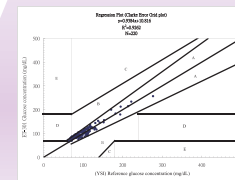


Fig. 1. Bland-Altman Error Grid analysis of the EasyTouch GCU Monitoring System. 200 glucose readings were plotted against the Y8 reference method.

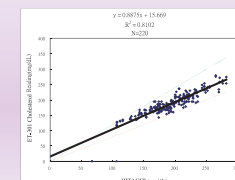


Fig. 2. Linear regression analysis of the EasyTouch GCU Monitoring System against the HFA204 reference method. A total of 200 cholesterol readings were plotted.

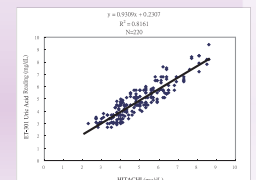


Fig. 3. Linear regression analysis of the EasyTouch GCU Monitoring System against the HFA204 reference method. A total of 200 uric acid readings were plotted.

Glucose

Cholesterol

Uric Acid

Meter identifies the strips automatically

Specifications	EasyTouch	EasyTouch	EasyTouch
Mode	Glucose	Cholesterol	Uric Acid
Measuring Range	20-600 mg/dL (1.1-33.3 mmol/L)	100-400 mg/dL (2.6-10.4 mmol/L)	3-20 mg/dL (179-1190 μmol/L)
Memory Capacity	200 test results	50 test results	50 test results
Test Time	10 seconds	150 seconds	20 seconds
Operating Condition	Temperature Humidity	57.2-104°F [14-40°C] ≤ 85% humidity	
Meter Storage Condition	Temperature Humidity	14-104°F [-10-60°C] ≤ 95% humidity	
Sample Volume	≥ 4 μl	≥ 15 μl	≥ 4 μl
Sample Type		Capillary whole blood	
Hematocrit Range		30-50%	
Power Supply		1.5V (AAA)X2	
Battery Life		More than 1000 times	
Display		LCD display (35x45mm)	
Dimensions HxWxD(mm)		86 x 64 x 22	
Weight		59 grams, without battery	
Technology Used		Amperometric enzyme electrode	
Time & Date Display		Yes	
Average Result	7 / 14 / 28 Days	—	—
Power On & off		Automatically	
Strip Type		Siphonal Strip(Capillary Action)	
Warranty		2 Years	

Glucose

Cholesterol

Meter identifies the strips automatically

Specifications	EasyTouch	EasyTouch
Mode	Glucose	Cholesterol
Measuring Range	20-600 mg/dL (1.1-33.3 mmol/L)	100-400 mg/dL (2.6-10.4 mmol/L)
Memory Capacity	200 test results	100 test results
Test Time	10 seconds	150 seconds
Operating Condition	Temperature Humidity	57.2-104°F [14-40°C] ≤ 85% humidity
Meter Storage Condition	Temperature Humidity	14-104°F [-10-60°C] ≤ 95% humidity
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Power Supply		1.5V (AAA)X2
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Dimensions HxWxD(mm)		86 x 64 x 22
Weight		59 grams, without battery
Technology Used		Amperometric enzyme electrode
Time & Date Display		Yes
Average Result	7 / 14 / 28 Days	—
Power On & off		Automatically
Strip Type		Siphonal Strip(Capillary Action)
Warranty		2 Years

Glucose

Uric Acid

Meter identifies the strips automatically

Specifications	EasyTouch	EasyTouch
Mode	Glucose	Uric Acid
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Time & Date Display		Yes
Average Result	7 / 14 / 28 Days	—
Power On & off		Automatically
Strip Type		Siphonal Strip(Capillary Action)
Warranty		2 Years

Glucose

Specifications	EasyTouch
Mode	Glucose
Measuring Range	20-600 mg/dL (1.1-33.3 mmol/L)
Memory Capacity	200 test results
Test Time	10 seconds
Operating Condition	Temperature Humidity
Meter Storage Condition	Temperature Humidity
Sample Volume	≥ 4 μl
Sample Type	Capillary whole blood
Hematocrit Range	30-50%
Power Supply	1.5V (AAA)X2
Battery Life	More than 1000 times
Display	LCD display (35x45mm)
Dimensions HxWxD(mm)	86 x 64 x 22
Weight	59 grams, without battery
Technology Used	Amperometric enzyme electrode
Time & Date Display	Yes
Average Result	7 / 14 / 28 Days
Power On & off	Automatically
Strip Type	Siphonal Strip(Capillary Action)
Warranty	2 Years

www.easytouchmeter.com.tw

service@bioptik.com.tw



EC REP MT Promedl Consulting GmbH
 Altenhofstrasse 80, 66386 St.
 Ingbert / Hassel, Germany
 Tel: +49-6894-581020



Rev.A1 02/12

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2096815-1

Manufacturer: Bioptik Technology, Inc.
No. 188,
Jhonghua South Road,
Gongguan Village, Jhunan Township,
Miaoli County, 35057
Taiwan

Products:

- Blood Glucose Monitoring System
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Triglyceride Monitoring System
- Blood Ketone Monitoring System
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring Systems
- Blood Glucose/ Ketone Monitoring System
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/ Cholesterol/Triglyceride Monitoring System
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring Systems
- Blood Glucose/ Cholesterol/ Uric Acid/Hemoglobin/Triglyceride Monitoring System

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 238515366-090

Effective date: 2022-05-21

Expiry date: 2025-05-26

Issue date: 2022-05-21



TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

**Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)**

Registration No.: HL 2096815-1

Manufacturer: Bioptik Technology, Inc.
No. 188,
Jhonghua South Road,
Gongguan Village, Jhunan Township,
Miaoli County, 35057
Taiwan

- Blood Pressure/Glucose/Cholesterol Monitoring System (assessment limited to Glucose/Cholesterol Monitoring)

Report No.: 238515366-090
Effective date: 2022-05-21
Expiry date: 2025-05-26
Issue date: 2022-05-21



Poxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2096815-1

Manufacturer: Bioptik Technology, Inc.
No. 188,
Jhonghua South Road,
Gongguan Village, Jhunan Township,
Miaoli County, 35057
Taiwan

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Bioptik Technology, Inc., Tainan Plant 3F and 4F, No. 1, Guanghua St. Yongjiu Village, Xinshi Dist., Tainan City, 74449 Taiwan	Blood Glucose Test Strips

Report No.: 238515366-090
Effective date: 2022-05-21
Expiry date: 2025-05-26
Issue date: 2022-05-21



Puxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.