GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1634048**

Din От **22.05.2026 16:34**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1010600028048

Denumirea
Наименование

Societatea cu Răspundere Limitată "BIOSISTEM MLD"

Digitally signed by Poiata Vitalie
Date: 2026.06.04 11:26:58 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **06.06.2026 16:34**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul guvernamental integrat EVO / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Интегрированный правительственный портал EVO.

Generat și semnat de Portalul guvernamental integrat EVO la **22.05.2026 16:34**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul guvernamental integrat EVO (evo.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Интегрированный правительственный портал EVO (evo.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Интегрированный правительственный портал EVO (msign.gov.md)

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

Declaration of Conformity

CE 0123

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, P. R. China
Manufacturer SRN:	CN-MF-000014156
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Automatic Urinalysis System
Model:	EU-5300Pro、EU-5600Pro
Basic UDI-DI:	69449040AB3100004ZW

Intended Purpose: Automatic Urinalysis System is an in vitro diagnosis device used for quantitative tests on human urine in laboratory environment. Clinically, the analyzer identifies and analyzes the formed elements in human urine, including red blood cell, white blood cell, White blood cell clump, bacteria, yeast, squamous epithelial cell, non-squamous epithelial cell, crystal, hyaline cast, unclassified cast, mucous strands, sperm, coccus, rod, mono-hydrate calcium oxalate crystal, di-hydrate calcium oxalate, uric acid and triple phosphate crystal.

The system can also used for semi-quantitative or qualitative testing of human urine with urinalysis test strips. It is suitable for routine clinical urine examination. The test items include: leukocyte, nitrite, urobilinogen, protein, potential of hydrogen, blood, specific gravity, ketone, bilirubin, glucose, Vitamin C, microalbumin, creatinine, calcium, color and turbidity.

Classification:	Class B (According to Rule 6 of IVDR annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	35918

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:	/
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	V13 044751 0348
Start of CE-Marking:	2023-9-6

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue:	Shenzhen, 2025.11.26
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation Department

Declaration of Conformity V 2.0

Attachment of Declaration of Conformity: Applied Standards List-V2.0

Applied Standards List

Product: Automatic Urinalysis System

Model: EU-5300Pro、EU-5600Pro

Standards Applied:

EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)
EN ISO 18113-3:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2022)
ISO 15223-1:2021/A1：2025	Medical devices-Symbols tobe used with information to besupplied by the manufacturerPart 1:General requirements AMENDMENT 1: Addition of definedterm for authorized representativeand modified EC REP symbol to not becountry or region specific
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 61010-1:2010+A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61326-1:2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
IEC 61326-2-6:2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro

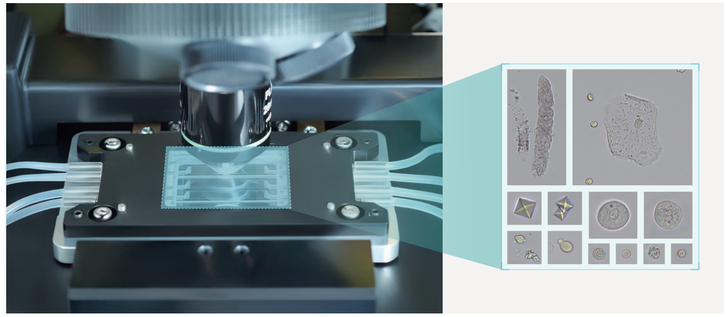
Declaration of Conformity V 2.0

	diagnostic (IVD) medical equipment
IEC 62304:2015	Medical device software- Software life cycle processes
IEC 62366-1：2015	Medical devices — Application of usability engineering to medical devices
EN IEC 63000：2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN ISO 20916:2024	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Digitally signed by Prodan Sveatoslav
Date: 2025.12.03 13:05:02 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA
EUROPEANĂ

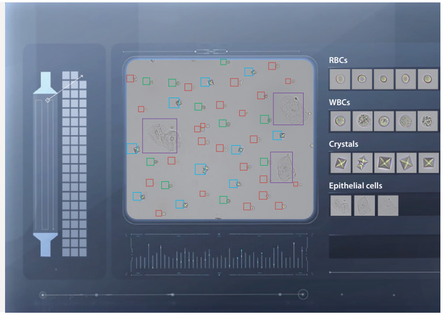
2K full-color clear imaging, reducing the rate of manual microscopic review for positive samples

Colorful imaging technique which is close to manual microscopic satisfies what you need for releasing a report



High analysis volume for sediment particles to avoid missed diagnosis of positive samples

The system captures up to 60 clear images from the samples. Utilizing advanced algorithm, the system can precisely identify various types of formed elements from panoramic images, thereby minimizing the chances of missed positive samples.



EU-5300 Pro

Automated Urinalysis System

Testing principles

Dry chemistry: Photoelectric colorimetry, refractometry, and Nephelometry method.
Formed elements: Machine vision (Digital imaging technology)

Reportable parameters

Physical: Specific gravity, color, and turbidity
Dry chemistry: 11/14 items

LEU, leukocyte	NIT, nitrite
URO, urobilinogen	pH, power of hydrogen
PRO, protein	BLD, erythrocyte
BIL, bilirubin	MCA, micro albumin
GLU, glucose	CRE, creatinine
VitC, vitamin C	CA, calcium
SG, specific gravity	P/C, protein-to-creatinine ratio*
KET, ketones	A/C, microalbumin-to-creatinine ratio*

Note: Parameters indicated with an asterisk (*) are intended for calculated parameters

Formed elements: 31kinds

RBCs (total)	BACT, bacteria
Normocytic, Nor-RBC	BACTc, coccus
Macrocyte, Mac-RBC	BACTr, rod
Microcyte, Mic-RBC	YST, Yeast
Crenocyte, Cre-RBC	Squamous epithelial cell, SEC
Annular RBCs, Ann-RBC	Non squamous epithelial cell, NEC
Acanthocytes, Aca-RBC	CRYS, Crystals
Humped Spherocytes, Hpd-RBC	Mono-hydrate calcium oxalate crystal, Caoxm
Jagged RBCs, Jag-RBC	Di-hydrate calcium oxalate crystal, Caoxd
Ghost RBCs, Gho-RBC	Uratic crystal, URA
Fragmented RBC, Fra-RBC	Triple phosphate crystal TRP
Other abnormal RBCs, Oab-RBC	HYAC, hyaline cast
Anisocytosis Ratio, Ani-Ratio	UNCC, unclassified cast
MorInfo-RBC	MUC, mucous strands
WBC, white blood cells	Sperm, SPRM
WBCC, white blood cells clump	

Throughput

Dry chemistry mode: ≥160 tests/ hour
Formed element mode: ≥70 tests/ hour
Hybrid mode: ≥70 tests/ hour

Automated focusing

The system automatically performs the focusing process, without the need for manual operation or the use of focus reagents

STAT function

Independent STAT positions for emergency samples at any time

Strips loading capacity

200

Sample Volume

2.5ml minimum required sample volume

Sample type

Native urine sample

Barcode

Built-in barcode reader

Tube specification

Length ≤110mm Diameter 15-16mm

Communication

Bi-direction LIS, automated barcode identification for testing

Dimensions and Weight

WxDxH: 600x770x530(mm) / ≤71.5Kg

www.mindray.com

P/N:ENG-EU-5300 Pro-210285X6P-20230822

mindray
healthcare within reach

EU-5300 Pro

Automated Urinalysis System

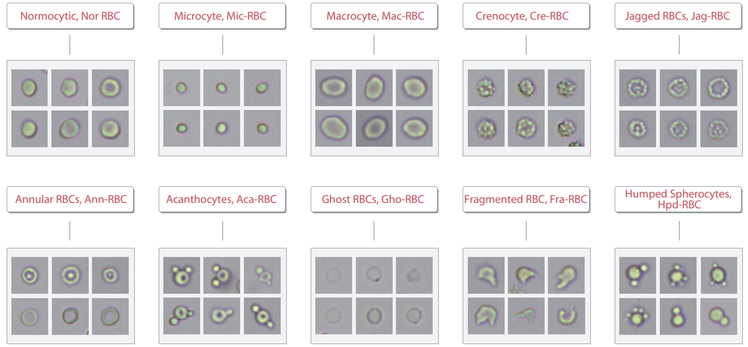
Unveiling the Unseen by Unlocking Unparalleled Clarity

Three features integrated in a single system to manage the unique workflow needs of your lab

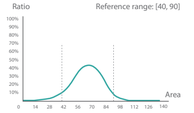
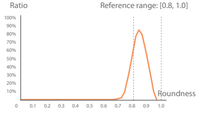
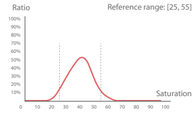
The integration of dry chemistry, formed element, and RBC phase analysis leads to a great improvement in time and space management efficiency. Even a single person can easily manage the TAT requirements during the peak hours of your lab.

Coming standard with RBC phase parameters to help rapidly identify the source of hematuria

The system can automatically provide parameters for various types of urinary RBCs, presenting histograms that clearly depict the size, shape, and hemoglobin content of these cells. By analyzing the results of RBC morphological variations (MorInfo-RBC: homogeneous/heterogeneous/mixed) and utilizing RBC morphological images, a thorough review and validation process can be conducted to identify the source of hematuria rapidly and precisely.



RBC phase histograms showing the reference ranges and their clinical significance

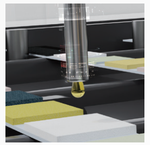
	RBC size histogram	RBC shape histogram	RBC chroma histogram
Histogram			
Unit of measurement	um^2	Dimensionless	Dimensionless
Normocytic, Nor-RBC	40-90	0.8-1.0	25-55
Macrocyte, Mac-RBC	50-85	0.75-1.0	25-55
Microcyte, Mic-RBC	20-55	0.8-1.0	35-60
Crenocyte, Cre-RBC	15-50	0.75-1.0	35-60
Annular RBCs, Ann-RBC	15-70	0.7-1.0	10-50
Acanthocytes, Aca-RBC	45-80	0.6-0.9	30-60
Humped Spherocytes, Hpd-RBC	40-85	0.55-0.8	25-55
Jagged RBCs, Jag-RBC	20-75	0.75-1.0	10-50
Ghost RBCs, Gho-RBC	10-50	0.75-1.0	5-18
Fragmented RBC, Fra-RBC	20-55	0.6-0.9	30-60
Clinical significance	Left shift indicates a decrease in size Right shift indicates an increase in size	The roundness decreases when there is any abnormality	Left shift indicates a decrease in hemoglobin concentration Right shift indicates an increase in hemoglobin concentration

Dry chemistry analysis delivers precise results that are better aligned with the analysis of formed elements

The test strip for dry chemistry analysis are optimized to enable precise sampling, thereby ensuring accurate results, consistent performance, and greater ease of use.

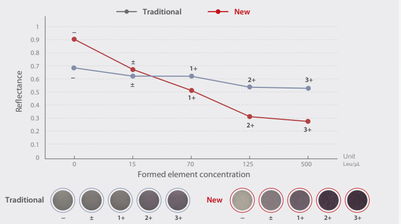
Accurate sampling

New strips



The optimized test strip and sampling method result in an increase in the color development speed and the resolution between gradients

Comparison of resolution at different gradients between traditional and new test strips



Safety and ease of use, and efficient review

The system supports running urine samples with closed tubes, ensuring enhanced levels of biosafety.
With the inclusion of Mindray data management software—LabXpert, the system shows dry chemistry, urine formed elements, and RBC phase results on a single screen, significantly improving the efficiency of report validation.