

**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ **A2300708**

din  
от **18.01.2023**

**1. Destinația / Назначение**

Pentru participarea la proceduri de achiziții publice

**2. Date despre contribuabil / Информация о налогоплательщике**

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
<b>BIOSISTEM MLD S.R.L.</b>	1010600028048
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

**3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /**  
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:  
**0,00 lei/лей.**

**4. Valabil pînă la / Действителен до 02.02.2023**

**5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы**

Șef interimar DDF Rîșcani

Funcția/Dолжность

Digitally signed by Stoicov Ana  
Date: 2023.01.18 13:03:01 EET  
Reason: MoldSign Signature  
Location: Moldova

Semnătura/Подпись



STOICOV Ana

Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: **GOJAN Claudia**  
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 18.01.2023 ora 8:14:52  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)





# 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







## I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

### EXTRAS din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

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: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 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,**

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

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: 28.04.2021.

Specialist coordonator  
tel. 022-207-840



**Lazari Aliona**



EB 0358735



## **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

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

Scope: Design and development, production, distribution and servicing  
of instruments and reagents for clinical diagnostic.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92648791-40  
Effective date: 2022-12-12  
Expiry date: 2025-12-12  
Issue date: 2022-12-12

*J. Pyclik*



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

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain	Design and development, production, distribution and servicing of instruments and reagents for clinical diagnostic.
/02	BIOSYSTEMS S.A. Polígono Industrial Can Tapioles Naves 12, 13, 21, 22 08010, Montcada i Reixac – Barcelona, Spain	Labelling and assembling of reagents, warehousing and shipment of instruments and reagents for clinical diagnostic.

Report No.: 92648791-40  
Effective date: 2022-12-12  
Expiry date: 2025-12-12  
Issue date: 2022-12-12



*J. Pyclik*



TÜV Rheinland LGA Products GmbH  
Zertifizierungsstelle

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

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

Certificate Holder: **BIOSYSTEMS S.A.**  
Costa Brava 30  
08030 Barcelona  
Spain

including the locations according to annex

Scope: Design, development, manufacture, distribution, installation and service of instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Reagent labelling and assembly.  
Storage of raw materials for instruments, instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Dispatched or stored product.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-12-19 until 2025-12-18.  
First certification 1996

2022-12-15



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

No.	Location	Scope
/01	<b>BIOSYSTEMS S.A.</b> Costa Brava 30 08030 Barcelona Spain	Design, development, manufacture, distribution, installation and service of instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics.
/02	<b>BIOSYSTEMS, S.A.</b> Pol. Ind. Can Tapiolas Naves 12, 13, 21 y 22 08110 Montcada i Reixac (Barcelona) Spain	Reagent labelling and assembly. Storage of raw materials for instruments, instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics. Dispatched of stored product.

2022-12-15



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Declaration of Conformity



**Manufacturer:** Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Mindray Building, Keji 12th Road South, Hi-tech Industrial  
Park, Nanshan, Shenzhen, 518057, P. R. China

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80  
20537 Hamburg, Germany

**Product:** **Auto Hematology Analyzer**

**Model:** **BC-20s**  
Including reagents as following:  
**M-30D DILUENT**  
**M-30CFL LYSE**  
**PROBE CLEANSER**

**Classification:** The device not in IVDD annex II and not for self  
testing/performance evaluation

**Conformity Assessment Route:** IVDD Annex III(excluding Section 6)

**We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.**

**Standards Applied:**

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

**Start of CE-Marking:** 2015-3-31

**Place, Date of Issue:** Shenzhen, 2015-3-31

**Signature:** 

**Name of Authorized Signatory:** Mr.tan ChuanBin

**Position Held in Company:** Manager ,Technical Regulation



# Declaration of Conformity



**Manufacturer:** Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Mindray Building, Keji 12th Road South, Hi-tech Industrial  
Park, Nanshan, Shenzhen, 518057, P. R. China

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80  
20537 Hamburg, Germany

**Product:** **Auto Hematology Analyzer**

**Model:** **BC-30s**  
Including reagents as following:  
**M-30D DILUENT**  
**M-30CFL LYSE**  
**PROBE CLEANSER**

**Classification:** The device not in IVDD annex II and not for self  
testing/performance evaluation

**Conformity Assessment Route:** IVDD Annex III(excluding Section 6)

**We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.**

**Standards Applied:**

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

**Start of CE-Marking:** 2015-3-31

**Place, Date of Issue:** Shenzhen, 2015-3-31

**Signature:** \_\_\_\_\_ 

**Name of Authorized Signatory:** Mr.tan ChuanBin  
**Position Held in Company:** Manager ,Technical Regulation

Declaration of Conformity V 1.0

## Applied Standards List

**Product:** Auto Hematology Analyzer

**BC-20s, BC-30s**

Including reagents as following:

**M-30D DILUENT**

**M-30CFL LYSE**

**PROBE CLEANSER**

### Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003+A1: 2003	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
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and



## Declaration of Conformity V 1.0

	laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices
EN ISO13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes

# EC DECLARATION OF CONFORMITY

*In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC

**Manufacturer:** Türklab Tıbbi Mal. San. ve Tic. A.Ş.  
**Headquarters / Manufacturing Side:** İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - Turkey  
**Product:** Fecal Occult Blood (FOB) Test  
**Brand:** Rapidan® Tester, Toyo®, Info®, Labmen®  
**Classification:** Professional Use IVD, 98/79/EC  
**Conformity Assessment Route:** Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

**Standards Applied:** EN ISO 13485:2016  
EN ISO 14971:2012  
EN ISO 15223:2016  
EN ISO 18113-1:2011  
EN ISO 18113-2:2011  
EN ISO 23640:2015  
EN 13612:2002

**Revision No:** 5

**Place, Date of Issue:** İzmir, 08.03.2019

**Signature** Dr. Şahin Yağlıdere, Md  
General Manager

**TÜRLAB**  
TIBBİ MALZ. SAN. VE TİC. A.Ş.  
MERKEZ: İTOB OSB MAH. 10017 SK. NO:15 MENDERES / İZMİR  
FABRİKA: İTOB OSB MAH. 10017 SK. NO:2 MENDERES / İZMİR  
TEL: 0 232 376 80 81 FAX: 0 232 376 80 40  
MENDERES V.D. 079 009 6209







# Declaration of Conformity



According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

**Manufacturer:** Dirui Industrial Co., Ltd.  
95 Yunhe Street New& High Tech. Development Zone  
Changchun Jilin 130012 P.R. China

**Authorized Representative:** Emergo Europe

Molenstraat 15 2513 BH The Hague  
The Netherlands

**Medical Device :** Product Name: Reagent strips for Urinalysis

IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture  
(where applicable)

- |  |                                  |                     |
|--|----------------------------------|---------------------|
| DIRUI 1 ITEMS (GLU)                    | DIRUI 1 ITEMS (KET)              | DIRUI 1 ITEMS (PRO) |
| DIRUI 2 ITEMS (PRO, GLU)               | DIRUI 2 ITEMS (KET, GLU)         |                     |
| DIRUI 3 ITEMS (PRO, PH, GLU)           | DIRUI 3 ITEMS (PRO, KET, GLU)    |                     |
| DIRUI 4 ITEMS (PRO, PH, BLD, GLU)      | DIRUI 4 ITEMS (PRO, PH, SG, GLU) |                     |
| DIRUI 5 ITEMS (PRO, PH, BLD, KET, GLU) |                                  |                     |
| DIRUI 8 ITEMS                          | DIRUI H8                         |                     |
| DIRUI 9 ITEMS                          |                                  |                     |
| DIRUI A10                              | DIRUI H10                        | DIRUI E10           |
| DIRUI H11                              | DIRUI H11-MA                     | DIRUI M10           |
| DIRUI H11-800MA                        |                                  | DIRUI H10-800       |
| DIRUI H13-Cr                           | DIRUI H12-800MA                  |                     |
| DIRUI H13-Cr (H-800)                   | DIRUI H14-Ca                     |                     |
|  | DIRUI H14-Ca (H-800)             |                     |

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

**This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.**

Valid Since  
May 9<sup>th</sup>, 2012  
Changchun, China

Representative:

Yu Ge

Dirui Industrial Co., Ltd. 睿睿医疗科技

于歌 股份有限公司



(place and date of issue)

(name and signature or equivalent marking of authorized person)