



# BC "MOLDINDCONBANK" S.A.

## Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chișinău, 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. Московской, 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 în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243**.

Codul băncii MOLDMD2X329.

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*

*A. Sizy*  
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> |

## EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

### **Hereby DECLARES**

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

### **Directive on in Vitro Diagnostic Medical Devices (98/79/EC)**

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6<sup>th</sup>, 2012



Dr. Antonio Elduque  
Managing director  
BioSystems S.A.



• Certified Management  
System  
• EN ISO 9001  
• EN ISO 13485



## **CLINICAL CHEMISTRY – BIOCHEMISTRY:**

|                                       |                                    |
|---------------------------------------|------------------------------------|
| a-Amylase-Direct                      | Creatine Kinase (CK)               |
| a-Amylase-EPS                         | Creatine Kinase-MB (CK-MB)         |
| a-Amylase-Pancreatic                  | Creatinine                         |
| Acid Phosphatase (ACP)                | Fructosamine                       |
| Alanine Aminotransferase (ALT/GPT)    | Fructose                           |
| Albumin                               | g-Glutamyltransferase (g-GT)       |
| Alkaline Phosphatase (ALP)-AMP        | Glucose                            |
| Alkaline Phosphatase (ALP)-DEA        | Iron – Chromazurol                 |
| AspartateAminotranferase (AST/GOT)    | Iron – Ferrozine                   |
| Bilirubin (direct)                    | Iron Binding Capacity              |
| Bilirubin (total and direct)          | Lactate Dehydrogenase (LDH)        |
| Bilirubin (total)                     | Lactate Dehydrogenase (LDH) – IFCC |
| Calcium – Arsenazo                    | Lipase                             |
| Calcium – MTB                         | Magnesium                          |
| Cholesterol                           | Phosphorus                         |
| Cholesterol HDL                       | Protein (total)                    |
| Cholesterol HDL direct                | Protein (urine)                    |
| Cholesterol HDL Precipitating reagent | Pyridoxal Phosphate                |
| Cholesterol LDL direct                | Triglycerides                      |
| Cholesterol LDL Precipitating reagent | Urea/BUN-Color                     |
| Cholinesterase (CHE)                  | Urea/BUN-UV                        |
| Citrate                               | Uric Acid                          |

## **CLINICAL CHEMISTRY – TURBIDIMETRY:**

|                              |                                |
|------------------------------|--------------------------------|
| a1-acid Glycoprotein         | C-Reactive Protein (CRP)       |
| Albumin (Microalbuminuria)   | C-Reactive Protein-hs (CRP-hs) |
| Anti-Streptolysin O (ASO)    | Ferritin                       |
| Antithrombin III             | Immunoglobulin A (IgA)         |
| Apolipoprotein A-I (Apo A-I) | Immunoglobulin G (IgG)         |
| Apolipoprotein B (Apo B)     | Immunoglobulin M (IgM)         |
| b2-Microglobulin             | Prealbumin                     |
| Complement Component C3      | Rheumatoid Factors (RF)        |
| Complement Component C4      | Transferrin                    |

## **CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:**

|                                                        |                    |
|--------------------------------------------------------|--------------------|
| 17-Hydroxycorticosteroids                              | Hemoglobin A1C     |
| 17-Ketosteroids                                        | Hemoglobin A2      |
| 5-Aminolevulinic Acid (ALA) /<br>Porphobilinogen (PBG) | Metanephrines      |
| 5-Hydroxyindoleacetic acid (5-HIAA)                    | Vanilmandelic Acid |



## **CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:**

|                                     |                                             |
|-------------------------------------|---------------------------------------------|
| a-1-acid Glycoprotein Standard      | Biochemistry Calibrator (Human)             |
| Adenosine Deaminase (ADA) Standard  | Cholesterol HDL/LDL Calibrator              |
| Albumin (Microalbuminuria) Standard | CRP/CRP-hs Standard                         |
| Anti-Streptolysin O (ASO) Standard  | Ferritin Standard                           |
| Antithrombin III Standard           | Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard |
| Apolipoprotein A-I Standard         | Prealbumin Standard                         |
| Apolipoprotein B Standard           | Protein Calibrators                         |
| b2-Microglobulin Standard           | Protein (urine) Standard                    |
| Bilirubin Standard                  | Rheumatoid Factors (RF) Standard            |
| Biochemistry Calibrator             |                                             |

## **CLINICAL CHEMISTRY – INSTRUMENTS:**

|     |         |
|-----|---------|
| A15 | BA400   |
| A25 | BTS-350 |

## **CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:**

|                                      |                              |
|--------------------------------------|------------------------------|
| a-Amylase-Direct                     | Creatine Kinase (CK)         |
| a-Amylase-Pancreatic                 | Creatine Kinase-MB (CK-MB)   |
| Adenosine Deaminase (ADA)            | Creatinine                   |
| Alanine Aminotransferase (ALT/GPT)   | g-Glutamyltransferase (g-GT) |
| Albumin                              | Glucose                      |
| Alkaline Phosphatase (ALP)-AMP       | Iron Ferrozine               |
| Alkaline Phosphatase (ALP)-DEA       | Lactate dehydrogenase (LDH)  |
| Aspartate Aminotransferase (AST/GOT) | Lipase                       |
| Bilirubin (direct)                   | Magnesium                    |
| Bilirubin (total)                    | Phosphorus                   |
| Calcium-Arsenazo                     | Protein (total)              |
| Cholesterol                          | Protein (urine)              |
| Cholesterol HDL direct               | Triglycerides                |
| Cholesterol LDL direct               | Urea/BUN UV                  |
|                                      | Uric acid                    |



## **CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:**

|                                |                                    |
|--------------------------------|------------------------------------|
| Albumin (Microalbuminuria)     | Ferritin                           |
| Anti-Streptolysin O (ASO)      | Hemoglobin A1C-Turbi (HbA1C-Turbi) |
| Antithrombin III               | Immunoglobulin A (IgA)             |
| Complement Component C3        | Immunoglobulin G (IgG)             |
| Complement Component C4        | Immunoglobulin M (IgM)             |
| C-Reactive Protein (CRP)       | Rheumatoid Factors (RF)            |
| C-Reactive Protein-hs (CRP-hs) | Transferrin                        |

## **CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:**

|                                       |                                 |
|---------------------------------------|---------------------------------|
| ADA Controls                          | Hemoglobin A1C Control (Normal) |
| Biochemistry Control Serum (Human) I  | Hemoglobin A2 Control           |
| Biochemistry Control Serum (Human) II | Lipid Control Serum I           |
| Biochemistry Control Serum I          | Lipid Control Serum II          |
| Biochemistry Control Serum II         | Protein Control Serum I         |
| CK-MB Control Serum                   | Protein Control Serum II        |
| Control Urine                         | Rheumatoid Control Serum I      |
| Fertility Biochemistry Control        | Rheumatoid Control Serum II     |
| Hemoglobin A1C Control (Elevated)     |                                 |

## **AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):**

|                                               |                                                |
|-----------------------------------------------|------------------------------------------------|
| Anti-Adrenal Cortex Antibodies (AACA)         | Anti-Thyroid Antibodies (ATA)                  |
| Anti-Endomysium Antibodies (AEA)              | Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)       |
| Anti-Islet Cell Antibodies (AICA)             | Autoantibodies MsK/MsS (AA-MsK/MsS)            |
| Anti-Keratin Antibodies (AKA)                 | Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)    |
| Anti-Mitochondrial Antibodies (AMA)           | Autoantibodies RK/RS (AA-RK/RS)                |
| Anti-nDNA antibodies (nDNA)                   | Autoantibodies RL/RK/RS (AA-RL/RK/RS)          |
| Anti-Neutrophil Cytoplasmic Antibodies (ANCA) | Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)        |
| Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)     | Glomerular Basement Membrane Antibodies (GBMA) |
| Anti-Nuclear Antibodies RL (ANA-RL)           |                                                |
| Anti-Skin Antibodies (ASA)                    |                                                |
| Anti-Smooth Muscle Antibodies (ASMA)          |                                                |
| Anti-Striated Muscle Antibodies (AStMA)       |                                                |



## ***AUTOIMMUNITY – ELISA:***

|                                                |                                                       |
|------------------------------------------------|-------------------------------------------------------|
| ANA Screening                                  | Anti-MPO Antibodies                                   |
| Anti-Annexin V IgG/IgM (ANX)                   | Anti-Nucleosome Antibodies (NCL)                      |
| Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)         | Anti-Phospholipid IgG/IgM (APLA)                      |
| Anti-Cardiolipin Antibodies (ACA-IgG/IgM)      | Anti-PR3 Antibodies                                   |
| Anti-Centromere B Antibodies (CENP-B)          | Anti-Ribosomal P Antibodies (Rib P)                   |
| Anti-Citrullinated Protein Antibodies (ACPA)   | Anti-Scl70 Antibodies                                 |
| Anti-Deamidated Gliadin Peptides IgA (DGP IgA) | Anti-Sm Antibodies                                    |
| Anti-Deamidated Gliadin Peptides IgG (DGP IgG) | Anti-Sm/RNP Antibodies                                |
| Anti-dsDNA Antibodies                          | Anti-SSA (Ro) Antibodies                              |
| Anti-GBM Antibodies - EIA (GBM)                | Anti-SSB (La) Antibodies                              |
| Anti-Gliadin Antibodies (AGA-IgG/IgA)          | Anti-Thyroglobulin Antibodies (Anti-Tg)               |
| Anti-Histones Antibodies (HIST)                | Anti-Thyroid Peroxidase Antibodies (Anti-TPO)         |
| Anti-Insulin Antibodies (INS)                  | Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA) |
| Anti-Jo1 Antibodies                            | Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG) |
| Anti-M2 Antibodies (M2)                        | ASCA-IgG/IgA (ASCA)                                   |
|                                                | ENA 4-Profile                                         |
|                                                | ENA 6-Screening                                       |

## ***AUTOINMUNIDAD – INSTRUMENTOS: AUTOIMMUNITY – INSTRUMENTS:***

iPRO



### ***RAPID TESTS – LATEX AGGLUTINATION:***

Anti-Streptolysin O (ASO) - Slide  
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

### ***INFECTIOUS IMMUNOLOGY – SYPHILIS:***

RPR-Carbon

TPHA

### ***INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:***

Febrile Serodiagnostics Multiscreening  
Febrile Serodiagnostics Salmonella  
Brucella abortus  
Brucella abortus, Rose Bengal  
Proteus Ox19  
Salmonella paratyphi AH  
Salmonella paratyphi AO  
Salmonella paratyphi BH  
Salmonella paratyphi BO  
Salmonella paratyphi CH  
Salmonella paratyphi CO  
Salmonella typhi H  
Salmonella typhi O  
Brucella Positive Control  
Proteus Positive Control  
Salmonella Positive Control  
Serology Negative Control



# 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 H12-800MA                  | DIRUI H10-800       |
| DIRUI H13-Cr                           | DIRUI H14-Ca                     |                     |
| DIRUI H13-Cr (H-800)                   | 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

(place and date of issue)

Representative:

Yu Ge

Dirui Industrial Co., Ltd.

于歌

(name and signature or equivalent  
marking of authorized person)

