



REPUBLICA MOLDOVA

# LICENȚĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul  
(adresa juridică) a titularului de licență

Societatea cu Răspundere Limitată  
"BIOSISTEM MLD"

mun. Chișinău, str. Albișoara, 16/1, ap. 7

Data și numărul certificatului de  
înregistrare de stat a titularului de licență

12.08.2010 MD 0101250

Numărul de înregistrare  
a întreprinderii sau IDNO

1010600028048

Codul fiscal

Genul de activitate, integral sau parțial,  
pentru a cărui desfășurare se eliberează licența

\* Importul, comercializarea, asistența tehnică  
și reparația dispozitivelor medicale \*

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1) 19.10.2012; 2) 14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

Semnătura conducătorului  
autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC



Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere,  
în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.



# 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  
in moneda nationala 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

*L. Svirepova*  
semnătura

MD 0101250





**„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.**  
**Secția fonduri speciale și informații curente**

**EXTRAS**  
**din Registrul de stat al persoanelor juridice**

nr. 14419 din 11.07.2016

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.**

Modul de constituire: **nou creată.**

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, IDNP 0983103892591,**

Asociați:

**1. POIATA VITALIE , IDNP 0983103892591**

**cota 1803.60 lei, ce constituie 33,4 %**

**2. NASEDCHIN ALEXANDR , IDNP 2002001070747**

**cota 1798.20 lei, ce constituie 33,3 %**

**3. KOJEVNIKOV DMITRII , IDNP 0972305012362**

**cota 1798.20 lei, ce constituie 33,3 %.**

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: 11.07.2016.

Specialist principal  
tel. 022-266-252

  
**Lazari Aliona**



## **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>Alexandru 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 (AACCA)        | 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

# Certificate

Standard **ISO 9001:2015**

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

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

Scope: Design, development, manufacture, distribution, servicing of:  
-Instruments and reagents for clinical diagnostic.  
-Instruments and reagents for agro-alimentary analysis.  
Distribution and service of reagents and instruments for veterinary diagnosis.

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

Validity: The certificate is valid from 2019-12-19 until 2022-12-18.  
First certification 1996

2019-12-20

TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

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# Annex to certificate

Standard **ISO 9001:2015**

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

| No. | Location                                                                                      | Scope                                                                                                                                                                                                                                                           |
|-----|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /02 | BIOSYSTEMS S.A.<br>Pol. Ind. Can Tapioles<br>naus 7-12-13<br>08110 Montcada i Reixac<br>Spain | Labeling and assembly of reagent. Storage,<br>and shipping of: - Instruments and reagents<br>for diagnosis and reagents for clinical<br>diagnosis.- Instruments and reagents for agri-<br>food analysis.- Instruments and reagents for<br>veterinary diagnosis. |

2019-12-20



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

Page 1 of 1

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[www.tuv.com](http://www.tuv.com)

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# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**BIOSYSTEMS S.A.**  
**Costa Brava 30**  
**08030 Barcelona**  
**Spain**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and development, manufacture, distribution and  
servicing of instruments and reagents for  
clinical diagnostic  
(see attachment for sites included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-08  
Certificate Registration No.: SX 60145545 0001  
An audit was performed. Report No.: 28300434 004  
This Certificate is valid until: 2022-12-12

Certification Body



Date 2020-01-08



D. Swiatko

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60145545 0001  
**Report No.:** 28300434 004

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

**Scope:**

Site included:

Polígono Industrial Can Tapioles  
Naves 7, 12 y 13  
08110 Montcada i Reixac  
Spain

Activity: Labelling and assembling of reagents,  
warehousing and shipment of instruments  
and reagents for clinical diagnostic

**Certification Body**



**Date: 2020-01-08**

**D. Swiatko**