



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

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



BIOSISTEM-MLD S.R.L.

Cod Fiscal: 1010600028048; IBAN: MD95ML000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

**Către Grupul de lucru pentru evaluarea
COP Nr. ocds-b3wdp1-MD-1583843037157
din 18.03.2020
din cadrul IMSP SCM Sf.Treime**

Declarație

Prin prezenta, SRL „Biosistem-MLD”, decalara ca, nu se află în următoarele situații:

- 1.Motive legate de plata impozitelor sau a contribuțiilor la asigurările sociale
- 2.Includerea în lista de interdicție a operatorilor economici
- 3.Motive legate de faliment, insolvență, conflicte de interese sau abateri profesionale Declarația, confirmată prin aplicarea semnăturii și ștampilei participantului

16.03.2020

_____Poiata Vitalie

L.Ș.

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2005964**

din
OT **03.03.2020**

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	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 până la / Действителен до 18.03.2020

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

Şef DDF Rîșcani
a DGAF mun.Chișinău

Funcția/Dолжность

L.Ş/ М.П.

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

Semnătura/Подпись

Ana STOICOV

Numele şi prenumele/Фамилия и имя



Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 03.03.2020 ora 14:40:30
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (5,31)

ORDIN DE PLATA NR.: 120		TIP.DOC. 1 :
		DATA EMITERII:17 martie 2020 :
=====		
PLATITI: 1000-00	LEI: Una Mie lei 00 bani	:
		:
		:
=====		
PLATITOR: (R) "BIOSISTEM MLD" S.R.L.	CONTUL DE PLATI/CODUL IBAN MD95ML000000002251429243 CODUL FISCAL :1010600028048 /	: : :
=====		
PRESTATORUL PLATITOR BC"Moldindconbank"S.A. suc."Invest" Chisinau	CODUL BANCII:MOLDMD2X329:	: :
=====		
BENEFICIAR (R) IMSP SPITAL UL CLINIC MUNICIPAL "SFANTA T REIME"	CONTUL DE PLATI/CODUL IBAN MD22ML000000000225166614 CODUL FISCAL :1003600152592 /	: : :
=====		
PRESTATORUL BENEFICIAR BC"Moldindconbank"S.A.	CODUL BANCII:MOLDMD2X	: :
=====		
DESTINATIA PLATII:"Pentru garantia pentr: u oferta la licitatie publica nr. ocds-b: 3wdpl-MD-1583843037157 din 18.03.2020	TIPUL TRANSFERULUI NORMAL/URGENT	:N: : : : :
		L.S.
=====		
CODUL TRANZACTIEI:001:		:
DATA PRIMIRII:17/03/2020	SEMNETURILE	:
DATA EXECUTARII:	EMITENTULUI	:
		:-----
CONDOCUTOR:		
(semnetura electronica)		
CONTABIL-SEF:Web Nasedchin Alexandr MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQEExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMAOGCSqG:SIB3DQEBcUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:DTE5MDEyODEwMTQwNFoxDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAkEMSww:YDVQQKE5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIElMRGBTUkwxEjAQBGNVBAsT		
L.S.		
(semnetura electronica)		
CONDOCUTOR:		
(semnetura manuala)		
CONTABIL-SEF:		
(semnetura manuala)		
SEMNETURA PRESTATORUL L.S.		
MOTIVUL REFUZULUI		
L.S.		

-----:
ORDIN DE PLATA NR.: 118 TIP.DOC. 1 :
DATA EMITERII:12 martie 2020 :
=====:
PLATITI: 3000-00 LEI: Trei Mii lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP SPITAL CONTUL DE PLATI/CODUL IBAN :
UL CLINIC MUNICIPAL "SFANTA T MD22ML000000000225166614 :
REIME" CODUL FISCAL :1003600152592 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
BC"Moldindconbank"S.A. :MOLDMD2X :
=====:
DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la licitatie publica nr. ocds-b3: NORMAL/URGENT :N:
wdp1-MD-1583843037157 din 18.03.2020 :
:
:
: L.S. :
=====:
CODUL TRANZACTIEI:001: :
DATA PRIMIRII:12/03/2020 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTOR:Web Poiata Vitalie :
MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBEowggRGMIIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTeQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxZjZA :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowY4xCzAJBgNVBAYTAk1EMScw:
YDVQKEx5NZWR1Y29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAST :
:
L.S. (semnatura electronica) :
CONDUCTOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNTURA PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
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Declaration of Conformity

This is to state that Technical Documentation (CL001, rev. 2.0) for product(s)

Coaguometer

(Model:CA-01, CA-02)

(IVD products other than those covered by Annex II, IVD for self-testing and devices for Performance evaluation according to manufacturer's declaration)

Manufactured by

CLINDIAG SYSTEMS CO., LTD

No.29 Zhiyuan Road, Jurong Economic Development Zone,

Zhenjiang, Jiangsu Province, China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 98/79/EEC for in Vitro Diagnostic Medical Device



For and on behalf of
CLINDIAG SYSTEMS CO.,LTD.


.....
Authorized Signature(s)

Mr. Xu Xin

General Manager

Valid from May, 2018 to May, 2023





REGISTRATION NO. 04716Q10011R0S

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of
Clindiag Systems Co., Ltd.

Registered Address: No.29 Zhiyuan Road, Jurong Economic Development
Zone, Jiangsu Province, P.R.China Postcode: 212400

Manufacturing Address: No.29 Zhiyuan Road, Jurong Economic
Development Zone, Jiangsu Province, P.R.China

Has been assessed and conformed to the following standard(s)
GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

**The Design, Development, Production and Service of
Semi-Automatic Biochemistry Analyzer, Coagulometer Analyzer,
Semi-Automatic Electrolyte Analyzer, Semi-Automatic Microplate
Reader, Microplate Washer, Automatic Urine Analyzer And Urine
Test Strips, Fully Automatic Biochemistry Analyzer, Fully
Automatic Hematology Analyzer, Vitro Diagnostic Reagent
(for export Only)**

Date of issue: January 15, 2019

Date of expiry: January 14, 2021

Director: *Zhang Chen*

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



**MANAGEMENT SYSTEM
CNAS C047 - Q**



Note: The Certificate Information are available on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn) or the Website of CMD (www.cmdc.com.cn).



REGISTRATION NO. 04716Q10000011

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Clindiag Systems Co., Ltd.

Registered Address: No.29 Zhiyuan Road, Jurong Economic Development
Zone, Jiangsu Province, P.R.China Postcode: 212400

Manufacturing Address: No.29 Zhiyuan Road, Jurong Economic
Development Zone, Jiangsu Province, P.R.China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485: 2016

The certificate is valid for the following scope:

**The Design, Development, Production and Service of
Semi-Automatic Biochemistry Analyzer, Coagulometer Analyzer,
Semi-Automatic Electrolyte Analyzer, Semi-Automatic Microplate
Reader, Microplate Washer, Automatic Urine Analyzer And Urine
Test Strips, Fully Automatic Biochemistry Analyzer, Fully
Automatic Hematology Analyzer, Vitro Diagnostic Reagent.**

(for export Only)

Date of issue: January 15, 2019

Date of expiry: January 14, 2021

Director:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

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 6th, 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) / 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

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

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

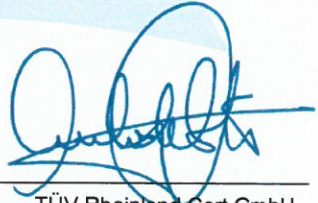
(including the locations according to annex)

Scope: Design, development, manufacture, distribution, installation and servicing of:
- Instruments and reagents for clinical diagnostic.
- Instruments and reagents for agro-alimentary analysis.
Distribution and servicing of instruments and reagents 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 2017-12-13 until 2019-12-18.
First certification 1996

2017-12-14


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	BIOSYSTEMS, S.A. Pl. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labelling and assembling of reagents. Warehousing and shipment of: -Instruments and Reagents for clinical diagnostic. -Instruments and Reagents for agro-alimentary analysis. -Instruments and Reagents for veterinary diagnosis.

2017-12-14



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

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: 2017-11-28

Certificate Registration No.: SX 60124804 0001

An audit was performed. Report No.: 28300434 002

This Certificate is valid until: 2019-12-12

Certification Body



Date 2017-11-28



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

**Attachment to
Certificate**

Registration No.: SX 60124804 0001
Report No.: 28300434 002

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 (Barcelona)
Spain

Scope:
Labelling and Assembling of reagents and
Warehousing and Shipment of instruments and
reagents for clinical diagnostic

Certification Body



Date: 2017-11-28

