

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

Nr.  
№ **A2201651**

din  
от **02.02.2022**

**1. Destinația / Назначение**

Pentru participare la proceduri de achizitii 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>	<b>1010600028048</b>
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
<b>Albisoara nr.16 bl.1 of.7</b>	<b>0150-SEC.RISCANI</b>

**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 17.02.2022**

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



Semnătura/Подпись

**Petru GRICIUC**

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 02.02.2022 ora 8:34:43  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (3,52)



# 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*

*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>

# Declaration of Conformity **CE**

**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-3600

Including reagents as following:

**M-30D DILUENT**

**M-30CFL LYSE**

**M-30R RINSE**

**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:** 2011-01-14

**Place, Date of Issue:** Shenzhen, 2011-01-14

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

**Name of Authorized Signatory:** Mr. Yang Long

**Position Held in Company:** Management Representative





America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**Certificate Holder:** Shenzhen Mindray Bio-Medical  
**Electronics Co., Ltd.**  
 Mindray Building  
 Keji 12th Road South  
 High-Tech Industrial Park  
 Nanshan  
 518057 Shenzhen  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** See Page 2 for Overall Scope Statement.

**Standard(s):** ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

**Report No.:** SH2005501

**Effective Date:** 2020-08-12

**Expiry Date:** 2023-06-30

Page 1 of 4

**Date of Issue:** 2020-08-20

Tina Israel  
 Manager, US Certification Body,  
 Medical and Health Services



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**Overall Scope Statement**

**Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag**

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Date of Issue: 2020-08-20

Tina Israel  
 Manager, US Certification Body,  
 Medical and Health Services





America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**Facility(ies):** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

**Facility Scopes:** Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

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Date of Issue: 2020-08-20

Tina Israel  
Manager, US Certification Body,  
Medical and Health Services



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 02

**Facility(ies)**

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
1203 Nanhuan Avenue, Guangming District, 518106  
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

**Facility Scopes:**

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

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Date of Issue: 2020-08-20

Tina Israel  
Manager, US Certification Body,  
Medical and Health Services











## 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) / 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-Annexin V IgG/IgM (ANX)  
Anti-b2-Glycoprotein 1 IgG/IgM  
(b2GP1)  
Anti-Cardiolipin Antibodies (ACA-  
IgG/IgM)  
Anti-Centromere B Antibodies (CENP-  
B)  
Anti-Citrullinated Protein Antibodies  
(ACPA)  
Anti-Deamidated Gliadin Peptides IgA  
(DGP IgA)  
Anti-Deamidated Gliadin Peptides IgG  
(DGP IgG)  
Anti-dsDNA Antibodies  
Anti-GBM Antibodies - EIA (GBM)  
Anti-Gliadin Antibodies (AGA-IgG/IgA)  
Anti-Histones Antibodies (HIST)  
Anti-Insulin Antibodies (INS)  
Anti-Jo1 Antibodies  
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies  
Anti-Nucleosome Antibodies (NCL)  
Anti-Phospholipid IgG/IgM (APLA)  
Anti-PR3 Antibodies  
Anti-Ribosomal P Antibodies (Rib P)  
Anti-Scl70 Antibodies  
Anti-Sm Antibodies  
Anti-Sm/RNP Antibodies  
Anti-SSA (Ro) Antibodies  
Anti-SSB (La) Antibodies  
Anti-Thyroglobulin Antibodies (Anti-Tg)  
Anti-Thyroid Peroxidase Antibodies  
(Anti-TPO)  
Anti-tTransglutaminase IgA Antibodies  
(Anti- tTG IgA)  
Anti-tTransglutaminase IgG Antibodies  
(Anti- tTG IgG)  
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

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

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



 **TÜVRheinland**<sup>®</sup>  
Precisely Right.

# Annex to certificate

Standard **ISO 9001:2015**

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

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

2019-12-20



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

Page 1 of 1

Klicken Sie hier, um Text einzugeben.

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

 **TÜVRheinland**<sup>®</sup>  
Precisely Right.

# 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**



## EC DECLARATION OF CONFORMITY

### MINI PARASEP SF FAECAL CONCENTRATOR

Apacor Ltd declares that the devices listed below conform to the relevant provisions of the EC Council Directive In Vitro Diagnostic Devices Directive 98/79/EC dated 27 October 1998. This compliance has been properly documented using checklist created from Annex III excluding point 6 of the Directive, linked to all supporting Technical Documentation.

MINI PARASEP SF CONCENTRATOR (148900)

Category: Other/General Device

CE Classification # 15051090

Apacor Ltd has a Quality System in place, which complies with ISO 9001 - 2008 regulations and agrees to develop, implement and maintain the Quality Management System to ensure continued adequacy and efficacy. Certificate Number GB96/8685.

This Declaration of Conformity is signed below, certifying these requirements have been met.

Janet MacKenzie

**General Manager – Apacor Limited**

3<sup>rd</sup> September 2014

# 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







# CERTIFICATE

**No J - 2670/4/2020**

This is to certify that:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**ITOB 10017 Sokak No: 2,**  
**Tekeli - Menderes İzmir / Turkey**

and

**Location**

**listed in Annex to the certificate**

is in conformance with

**EN ISO 9001:2015**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro medical devices:  
rapid tests intended for self-testing and for professional use,  
reagents and reagent products for blood grouping  
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **22.12.2020** to **21.12.2023**

Issued under the Contract No. 2897/JM/4/2020

Date of certification decision: 14.10.2020

Certificate bears a qualified signature.

Warsaw, 15.10.2020



AC 019  
QMS



Anna  
Małgorzata  
Wyroba  
Member of the Board

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.10.16  
08:47:33 +02'00'



# ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

**No J - 2670/4/2020**

This is to certify that the following Location:

**Factory 2: ITOB 10031 Sokak No: 15,  
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro medical devices:  
reagents and reagent products for blood grouping  
(gel cards and red blood cells reagents),  
professional use IVD tests and ECG electrodes**

**meets the requirements of the standard listed on the certificate**

Issued under the Contract No. 2897/JM/4/2020  
Date of certification decision: 14.10.2020  
Certificate bears a qualified signature.  
Warsaw, 15.10.2020



AC 019  
QMS



Anna  
Małgorzata  
Wyroba  
Member of the Board

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.10.16  
08:48:40 +02'00'

SOĞUK DAMGA VARDIR



T.C.  
TORBALI 6. NOTERLİĞİ  
Tel: 0232 664 70 07 Fax: 0232 664 70 17



№ 09971

## SERTİFİKA

No. M – 56/4/2020

İşbu sertifika ile;

**TÜRKLAB Tıbbi Mal. San. Tic. A.Ş.**  
**ITOB 10017 Sokak No:2, Tekeli-Menderes**  
**İzmir, Türkiye**

ve sertifika ekinde listelenmiş

### Lokasyon

Aşağıdaki faaliyetler kapsamında

**EN ISO 13485:2016**

ile uyumludur:

**invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kendi kendine test ve profesyonel kullanım için tasarlanmış hızlı testler, kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri) ve EKG elektrotları**

Polonya Test ve Sertifikasyon Merkezi tarafından yürütülen denetim, yukarıdaki kanıtları sağlamıştır. Bu Sertifika, Kuruluş tarafından yukarıdaki standarda uyulması kaydıyla geçerliliğini koruyacaktır.

**Bu sertifikanın geçerlilik tarihi: 22.12.2020'den 21.12.2023'e kadar**

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020

Sertifika kararının tarihi: 14.10.2020

Sertifika, yetkili imzayı taşımaktadır.

Varşova, 15.10.2020

Anna <<Elektronik İmza>>  
Malgorzata  
Wyroba  
Yönetim Kurulu Üyesi

POLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: [pcbc@pcbc.gov.pl](mailto:pcbc@pcbc.gov.pl)

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.

I hereby certify that this document has been translated from its English into Turkish truly and correctly by me. 03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN  
ERKAN ALTUNER

10 3 Aralık 2020







# CERTIFICATE

No M - 56/4/2020

This is to certify that:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş**  
**ITOB 10017 Sokak No: 2,**  
**Tekeli - Menderes İzmir / Turkey**

and

**Location**

**listed in Annex to the certificate**

is in conformance with

**EN ISO 13485:2016**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro medical devices:  
rapid tests intended for self-testing and for professional use,  
reagents and reagent products for blood grouping  
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020  
Date of certification decision: 14.10.2020  
Certificate bears a qualified signature.  
Warsaw, 15.10.2020

T.C.  
TORBALI 6. NOTERİ  
Selma ZİYREK

Anna  
Małgorzata  
Wyroba  
Member of the Board

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.10.16  
09:00:16 +02'00'



AC 019  
QMS





№ 09971

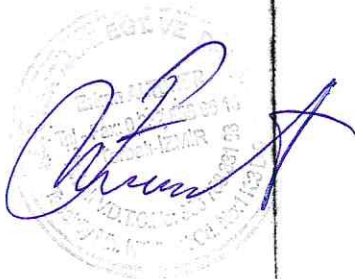
**SERTİFİKA EKİ****SADECE SERTİFİKA İLE BAĞLANTILI OLARAK GEÇERLİDİR**  
**No. M – 56/4/2020**

İşbu sertifika, aşağıda yer alan faaliyetler kapsamında Lokasyonun tasdiki için hazırlanmıştır:

**Fabrika 2: ITOB 10031 Sokak No: 15,**  
**Tekeli-Menderes İzmir, Türkiye****invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri), profesyonel kullanım IVD testleri ve EKG elektrotları****Sertifikada listelenen standardın gereksinimlerini karşılar.**Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020  
Sertifika kararının tarihi: 14.10.2020  
Sertifika, yetkili imzayı taşımaktadır.  
Varşova, 15.10.2020Anna <<Elektronik İmza>>  
Malgorzata  
Wyroba  
Yönetim Kurulu ÜyesiPOLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: [pcbc@pcbc.gov.pl](mailto:pcbc@pcbc.gov.pl)

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.

I hereby certify that this document has been translated from its English into Turkish truly and correctly by me. 03.12.2020

**SWORN TRANSLATOR / YEMİNLİ TERCÜMAN**  
ERKAN ALTUNER

03 Aralık 2020

T.C.  
TORBALI 6. NOTERİ  
Sema ZİYREK





## ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

### No M - 56/4/2020

This is to certify that the following Location:

№ 09971

**Factory 2: ITOB 10031 Sokak No: 15,  
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro medical devices:  
reagents and reagent products for blood grouping  
(gel cards and red blood cells reagents),  
professional use IVD tests and ECG electrodes**

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020  
Date of certification decision: 14.10.2020  
Certificate bears a qualified signature.  
Warsaw, 15.10.2020



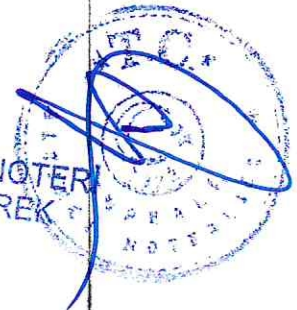
AC 019  
QMS



Anna  
Małgorzata  
Wyroba  
Member of the Board

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.10.16  
09:02:27 +02'00'

T.C.  
TORBALI 6. NOTER  
Seim ZIYREK







# CERTIFICATE

No M - 56/4/2020

This is to certify that:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş**  
**ITOB 10017 Sokak No: 2,**  
**Tekeli - Menderes İzmir / Turkey**

and

**Location**

**listed in Annex to the certificate**

is in conformance with

**EN ISO 13485:2016**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro medical devices:  
rapid tests intended for self-testing and for professional use,  
reagents and reagent products for blood grouping  
(gel cards and red blood cells reagents) and ECG electrodes**

The audit carried out by the Polish Centre of Testing and Certification has afforded evidence of the above

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **22.12.2020** to **21.12.2023**

Issued under the Contract No. 2897/JM/4/2020

Date of certification decision: 14.10.2020

Certificate bears a qualified signature.

Warsaw, 15.10.2020



AC 019  
QMS



Anna  
Małgorzata  
Wyroba  
Member of the Board

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.10.16  
09:00:16 +02'00'



# ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

**No M - 56/4/2020**

This is to certify that the following Location:

**Factory 2: ITOB 10031 Sokak No: 15,  
Tekeli - Menderes İzmir / Turkey**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro medical devices:  
reagents and reagent products for blood grouping  
(gel cards and red blood cells reagents),  
professional use IVD tests and ECG electrodes**

**meets the requirements of the standard listed on the certificate**

Issued under the Contract No. 2897/JM/4/2020  
Date of certification decision: 14.10.2020  
Certificate bears a qualified signature.  
Warsaw, 15.10.2020



AC 019  
QMS



Anna  
Małgorzata  
Wyroba  
Member of the Board

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2020.10.16  
09:02:27 +02'00'



TÜVRheinland®

## EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6  
Full Quality Assurance System  
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131743 0001

Report No.: 10042449 010

**Manufacturer:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Products:** In-vitro diagnostic Medical Devices for self-testing  
(see attachment for products included)  
Replaces Approval, Registration No.: HL 60088590 0001

**Expiry Date:** 2023-09-17

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2018-10-19

**Date:** 2018-10-19



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC  
concerning in vitro diagnostic medical devices with the identification number 0197.



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

**Attachment to  
Certificate**

**Registration No.:** HL 60131743 0001  
**Report No.:** 10042449 010

**Manufacturer:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Products:**

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Triglyceride Monitoring System
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Triglyceride Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin/Triglyceride Monitoring Systems
- Blood Pressure/Glucose/Cholesterol Monitoring Systems (assessment limited to Glucose/Cholesterol Monitoring)

**Date:** 2018-10-19

Notified Body  
  
*Allen Chen*  
Allen Chen  
Certifizierungsstelle



TÜVRheinland®

## EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6  
Full Quality Assurance System  
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131743 0001

Report No.: 10042449 010

**Manufacturer:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Products:** In-vitro diagnostic Medical Devices for self-testing  
(see attachment for products included)  
Replaces Approval, Registration No.: HL 60088590 0001

**Expiry Date:** 2023-09-17

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2018-10-19

**Date:** 2018-10-19



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC  
concerning in vitro diagnostic medical devices with the identification number 0197.

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

**Attachment to  
Certificate**

**Registration No.:** HL 60131743 0001  
**Report No.:** 10042449 010

**Manufacturer:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Products:**

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Triglyceride Monitoring System
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Triglyceride Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin/Triglyceride Monitoring Systems
- Blood Pressure/Glucose/Cholesterol Monitoring Systems (assessment limited to Glucose/Cholesterol Monitoring)

**Date:** 2018-10-19

Notified Body  
  
*Allen Chen*  
Allen Chen  
Certifizierungsstelle