

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

Nr.  
№ **A2501358**

din  
от **06.02.2025**

**1. Destinația / Назначение**

Pentru participarea la proceduri de achiziții publice

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

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

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

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

**4. Valabil pînă la / Действителен до 21.02.2025**

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

Șefă DDF Rîșcani

Funcția/Должность

Semnătura/Подпись

CĂUȘ Viorica

Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

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

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**







## 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**



# 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 în 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

## **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) / 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	
Biochemistry Control Serum (Human) I	Hemoglobin A1C Control (Normal)
Biochemistry Control Serum (Human) II	Hemoglobin A2 Control
Biochemistry Control Serum I	Lipid Control Serum I
Biochemistry Control Serum II	Lipid Control Serum II
CK-MB Control Serum	Protein Control Serum I
Control Urine	Protein Control Serum II
Fertility Biochemistry Control	Rheumatoid Control Serum I
Hemoglobin A1C Control (Elevated)	Rheumatoid Control Serum II

## **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-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



# Annex to certificate

Standard **ISO 9001:2015**

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

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

2022-12-15



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

Standard **ISO 9001:2015**

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

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

including the locations according to annex

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

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

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

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

Dispatched or stored product.

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

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

2022-12-15



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

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

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

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

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

*J. Pyclik*



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



# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

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

The scope of certification includes the following additional sites:

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

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



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

# Declaration of Conformity



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

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

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

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

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

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

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

**Standards Applied:**

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

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

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

**Signature:** 

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

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

# Declaration of Conformity



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

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

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

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

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

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

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

**Standards Applied:**

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

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

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

**Signature:** .....

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



Declaration of Conformity V 1.0

## Applied Standards List

**Product:** Auto Hematology Analyzer

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

Including reagents as following:

**M-30D DILUENT**

**M-30CFL LYSE**

**PROBE CLEANSER**

### Applied Standards:

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

## Declaration of Conformity V 1.0

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



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



## 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