



# 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: 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>



## CERTIFICAT

### privind lipsa sau existența restanțelor față de bugetul public național

Nr.  
№ A2101539

din  
от 04.02.2021

**1. Destinația / Назначение**

Pentru participare 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 19.02.2021**

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

**Șef DDF Riscani**  
a DGAF mun. Chișinău

L.Ș/ M.П.

Executor: Svetlana Slonovskaia

Numele și prenumele/Фамилия и имя

  
Semnătura/Подпись

**Viorica CĂUȘ**

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 04.02.2021 ora 11:29:26  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

**NOTA (1,45)**



# **BIOSISTEM-MLD S.R.L.**

c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău  
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.  
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

**Către Grupul de lucru pentru evaluarea**

**Procedurii de achiziție nr. 21035773**

**din 11.02.2021**

**din cadrul IMSP Clinica Universitară de Asistență Medicală**

**Primară a USMF Nicolae Testemițanu**

## **Declarație**

Prin prezenta, SRL „Biosistem-mld”, garanteaza ca reactivii și consumabilele sunt compatibile cu echipamentul beneficiarului și garantează prin asumarea de răspundere financiară deplină în cazul defecțiunilor produse echipamentului beneficiarului cauzate de calitatea necorespunzătoare a produselor

\_\_\_\_\_ Vitalie Poiata

**L.Ș.**



## 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 (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



# 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)



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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®**  
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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**





# Declaration of Conformity



According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

**Manufacturer:** Dirui Industrial Co., Ltd.  
95 Yunhe Street New& High Tech. Development Zone  
Changchun Jilin 130012 P.R. China

**Authorized Representative:** Emergo Europe

Molenstraat 15 2513 BH The Hague  
The Netherlands

**Medical Device :** Product Name: Reagent strips for Urinalysis

IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture  
(where applicable)

- |  |                                  |                     |
|--|----------------------------------|---------------------|
| DIRUI 1 ITEMS (GLU)                    | DIRUI 1 ITEMS (KET)              | DIRUI 1 ITEMS (PRO) |
| DIRUI 2 ITEMS (PRO, GLU)               | DIRUI 2 ITEMS (KET, GLU)         |                     |
| DIRUI 3 ITEMS (PRO, PH, GLU)           | DIRUI 3 ITEMS (PRO, KET, GLU)    |                     |
| DIRUI 4 ITEMS (PRO, PH, BLD, GLU)      | DIRUI 4 ITEMS (PRO, PH, SG, GLU) |                     |
| DIRUI 5 ITEMS (PRO, PH, BLD, KET, GLU) |                                  |                     |
| DIRUI 8 ITEMS                          | DIRUI H8                         |                     |
| DIRUI 9 ITEMS                          |                                  |                     |
| DIRUI A10                              | DIRUI H10                        | DIRUI E10           |
| DIRUI H11                              | DIRUI H11-MA                     | DIRUI M10           |
| DIRUI H11-800MA                        |                                  | DIRUI H10-800       |
| DIRUI H13-Cr                           | DIRUI H12-800MA                  |                     |
| DIRUI H13-Cr (H-800)                   | DIRUI H14-Ca                     |                     |
|  | DIRUI H14-Ca (H-800)             |                     |

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

**This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.**

Valid Since  
May 9<sup>th</sup>, 2012  
Changchun, China

Representative:  
Yu Ge  
Dirui Industrial Co., Ltd.  
于歌

(place and date of issue)

(name and signature or equivalent marking of authorized person)

# 认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306**

证书持有者:

**迪瑞医疗科技股份有限公司**  
统一社会信用代码: 91220101605902656F  
注册地址: 中华人民共和国吉林省长春市  
高新技术产业开发区云河街 95 号  
邮编: 130012  
经营地址: 同上述地址

认证范围:

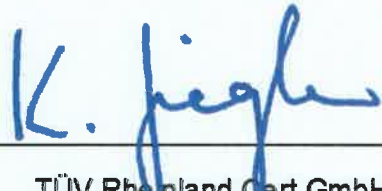
体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期:

证书有效期从 2018-05-03 至 2021-05-02。  
此证书须经过符合要求的监督审核保持有效。

2018-05-03

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306**

Certificate Holder: **Dirui Industrial Co., Ltd.**  
Unified Social Credit Code: 91220101605902656F  
Registration Address: 95 Yunhe Street,  
New & High Tech. Development Zone,  
Changchun City, Jilin Province 130012, P. R. China  
Operation Address: same as above

Scope: **Design and Development, Manufacture and Distribution of in Vitro  
Diagnostic Medical Test Systems**

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

Validity: **The certificate is valid from 2018-05-03 until 2021-05-02.  
It remains valid subject to satisfactory surveillance audits.**

2018-05-03



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Dirui Industrial Co., Ltd.**  
**95 Yunhe Street**  
**New & High Tech.**  
**Development Zone**  
**Changchun**  
**Jilin Province 130012**  
**China**

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

**Design and Development, Manufacture and Distribution of  
In vitro Diagnostic Medical Test Systems  
(see attachment for products and additional site included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

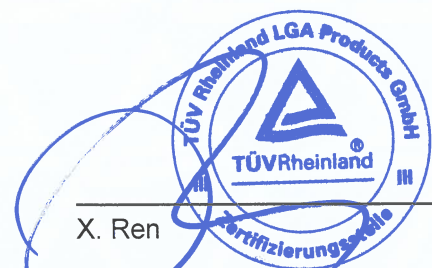
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-26  
Certificate Registration No.: SX 60127937 0001  
An audit was performed. Report No.: 15047317 007  
This Certificate is valid until: 2020-03-01

Certification Body



Date 2018-06-26



**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 60127937 0001  
**Report No.:** 15047317 007

**Organization:** Dirui Industrial Co., Ltd.  
95 Yunhe Street  
New & High Tech.  
Development Zone  
Changchun  
Jilin Province 130012  
China

**Scope:**

**Products:**

- Urine Test Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Immunochemistry Test Systems (Reagents, Analyzers, Controls)
- Vaginal Infections Test Systems (Reagents, Analyzers, Controls)

**Site included:**

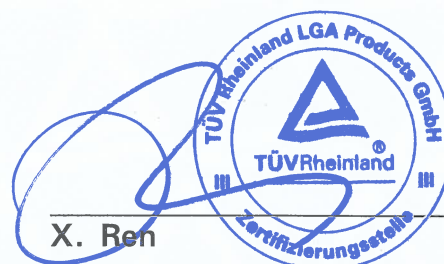
3333 Yiju Street, New & High Tech. Development Zone,  
Changchun, 130103 Jilin, China

Design and Development, Manufacture and Distribution of  
Urine Test Analyzers, Hematology Test Analyzers, Clinical  
Chemistry Test Analyzers, Immunochemistry Test Analyzers,  
Vaginal Infections Test Analyzers

**Certification Body**



**Date:** 2018-06-26





# 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.

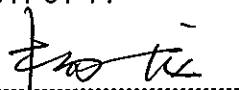
**Standards Applied:**

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



# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**Regulatory Requirements:    Audit/Certification Criteria**

**Australia**

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

**Brazil**

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

**Canada**

- Medical Device Regulations SOR/98-282, Part 1

**United States**

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

**Japan**

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

**Overall Scope Statement:**

**Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag**

Page 2 of 4

Date of Issue: 2019-11-25



( Dawn M. Tibodeau )  
Manager, Certification Body MHS



# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**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

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

**Facility Scopes:**

**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

Design and Development, Production and Distribution of  
Medical Electronic Equipment (including Patient Monitor and  
Accessories (NIBP House, NIBP Cuff, Sensor Cables including  
SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG  
Cables and Leadsets, Temperature Probe, Probe Cover),  
Vital Signs Monitor, Center Monitoring System, Telemetry  
Monitoring System, Pulse Oximeter, Defibrillator / Monitor  
and Accessories, Electrocardiograph, Anesthesia Machine  
and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic  
Equipment, Ultrasonic Transducer, Hematology Analyzer,  
Clinical Chemistry Analyzer, Microplate Reader, Microplate  
Washer for In-Vitro Diagnostic Use, Chemiluminescence  
Immunossay Analyzer, Flow Cytometer, Auto Sample  
Processing System, Auto Slide Maker and Stainer;) Reagents  
for Hematology Analyzer, Reagents for Clinical Chemistry  
Analyzer, Chemiluminescence Immunoassay Reagents,  
Chemiluminescence Immunoassav Calibrators and Controls;  
Disposable Anesthesia Mask, Reusable Anesthesia Mask,  
Respiratory Mask, Disposable Breathing Circuit, Reusable  
Breathing Circuit, Heat and Moisture Exchanger, Filter,  
Breathing Bag  
DUNS No: 65-467-1304

Page 3 of 4

Date of Issue: 2019-11-25



( Dawn M. Tibodeau )  
Manager, Certification Body MHS





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 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**

Page 2 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

**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

Page 3 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

**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

Page 4 of 4

Date of Issue: 2020-08-20

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