

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2202726**

din
от **18.02.2022**

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
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

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

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

4. Valabil pînă la / Действителен до 05.03.2022

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

Șef DDF Rîșcani

a DGDF
L.Ș/ M.П.

Executor: **Svetlana Slonovskaia**
Numele și prenumele/Фамилия и имя
tel: (022)823102



Semnătura/Подпись

Petru GRICIUC

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 18.02.2022 ora 8:17:43
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. Московской, 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 Balmuș

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





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

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

EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

Hereby DECLARES

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

Directive on in Vitro Diagnostic Medical Devices (98/79/EC)

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6th, 2012




Dr. Antonio Elduque
Managing director
BioSystems S.A.



• Certified Management System
• EN ISO 9001
• EN ISO 13485



CLINICAL CHEMISTRY – BIOCHEMISTRY:

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-EPS	Creatine Kinase-MB (CK-MB)
a-Amylase-Pancreatic	Creatinine
Acid Phosphatase (ACP)	Fructosamine
Alanine Aminotransferase (ALT/GPT)	Fructose
Albumin	g-Glutamyltransferase (g-GT)
Alkaline Phosphatase (ALP)-AMP	Glucose
Alkaline Phosphatase (ALP)-DEA	Iron – Chromazurol
AspartateAminotranferase (AST/GOT)	Iron – Ferrozine
Bilirubin (direct)	Iron Binding Capacity
Bilirubin (total and direct)	Lactate Dehydrogenase (LDH)
Bilirubin (total)	Lactate Dehydrogenase (LDH) – IFCC
Calcium – Arsenazo	Lipase
Calcium – MTB	Magnesium
Cholesterol	Phosphorus
Cholesterol HDL	Protein (total)
Cholesterol HDL direct	Protein (urine)
Cholesterol HDL Precipitating reagent	Pyridoxal Phosphate
Cholesterol LDL direct	Triglycerides
Cholesterol LDL Precipitating reagent	Urea/BUN-Color
Cholinesterase (CHE)	Urea/BUN-UV
Citrate	Uric Acid

CLINICAL CHEMISTRY – TURBIDIMETRY:

a1-acid Glycoprotein	C-Reactive Protein (CRP)
Albumin (Microalbuminuria)	C-Reactive Protein-hs (CRP-hs)
Anti-Streptolysin O (ASO)	Ferritin
Antithrombin III	Immunoglobulin A (IgA)
Apolipoprotein A-I (Apo A-I)	Immunoglobulin G (IgG)
Apolipoprotein B (Apo B)	Immunoglobulin M (IgM)
b2-Microglobulin	Prealbumin
Complement Component C3	Rheumatoid Factors (RF)
Complement Component C4	Transferrin

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

17-Hydroxycorticosteroids	Hemoglobin A1C
17-Ketosteroids	Hemoglobin A2
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)	Metanephrines
5-Hydroxyindoleacetic acid (5-HIAA)	Vanilmandelic Acid



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

a-1-acid Glycoprotein Standard	Biochemistry Calibrator (Human)
Adenosine Deaminase (ADA) Standard	Cholesterol HDL/LDL Calibrator
Albumin (Microalbuminuria) Standard	CRP/CRP-hs Standard
Anti-Streptolysin O (ASO) Standard	Ferritin Standard
Antithrombin III Standard	Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Apolipoprotein A-I Standard	Prealbumin Standard
Apolipoprotein B Standard	Protein Calibrators
b2-Microglobulin Standard	Protein (urine) Standard
Bilirubin Standard	Rheumatoid Factors (RF) Standard
Biochemistry Calibrator	

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-Pancreatic	Creatine Kinase-MB (CK-MB)
Adenosine Deaminase (ADA)	Creatinine
Alanine Aminotransferase (ALT/GPT)	g-Glutamyltransferase (g-GT)
Albumin	Glucose
Alkaline Phosphatase (ALP)-AMP	Iron Ferrozine
Alkaline Phosphatase (ALP)-DEA	Lactate dehydrogenase (LDH)
Aspartate Aminotransferase (AST/GOT)	Lipase
Bilirubin (direct)	Magnesium
Bilirubin (total)	Phosphorus
Calcium-Arsenazo	Protein (total)
Cholesterol	Protein (urine)
Cholesterol HDL direct	Triglycerides
Cholesterol LDL direct	Urea/BUN UV
	Uric acid



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

Albumin (Microalbuminuria)	Ferritin
Anti-Streptolysin O (ASO)	Hemoglobin A1C-Turbi (HbA1C-Turbi)
Antithrombin III	Immunoglobulin A (IgA)
Complement Component C3	Immunoglobulin G (IgG)
Complement Component C4	Immunoglobulin M (IgM)
C-Reactive Protein (CRP)	Rheumatoid Factors (RF)
C-Reactive Protein-hs (CRP-hs)	Transferrin

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)	Anti-Thyroid Antibodies (ATA)
Anti-Endomysium Antibodies (AEA)	Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Anti-Islet Cell Antibodies (AICA)	Autoantibodies MsK/MsS (AA-MsK/MsS)
Anti-Keratin Antibodies (AKA)	Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Anti-Mitochondrial Antibodies (AMA)	Autoantibodies RK/RS (AA-RK/RS)
Anti-nDNA antibodies (nDNA)	Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)	Glomerular Basement Membrane Antibodies (GBMA)
Anti-Nuclear Antibodies RL (ANA-RL)	
Anti-Skin Antibodies (ASA)	
Anti-Smooth Muscle Antibodies (ASMA)	
Anti-Striated Muscle Antibodies (AStMA)	



AUTOIMMUNITY – ELISA:

ANA Screening
Anti-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

CERTIFICAT DE AUTORIZARE

Prin prezentul este autorizata

SRL Biosistem-MLD
cu sediul 16/1-7, Albisoara Str., Chisinau, R.Moldova

de a reprezenta in calitate de ***distribuitor oficial*** in Republica
Moldova produsele

BIOSYSTEMS SA
cu sediul C/Costa Brava 30
08030 Barcelona (Spain)



Xavier Palomar
Area Manager
27-April-2013



Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARAȚIA DE CONFORMITATE CE № Ref . I-010 fiind parte integrală și indispensabilă al aparatului A-15 / A-25 / BA-400:

1. Rotor de reacție AC11485
2. Cuvă pentru ser AC10770
3. Soluție concentrată de spălare BO13416
4. Soluție de sistem BO11524
5. Lampă Halogenă LA10429
6. Ac pentru dozare AC11500
7. Reactivi biochimici, turbidimetrici, cromatografici, standarde, controale, aglutinație latex, indicate in anexa declarației de conformitate CE.

Produsele sus menționate sunt confecționate in conformitate cu standardele ISO 9001 si ISO 13485.



Xavier Palomar
Area Manager
27-April-2011



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

www.tuv.com



 **TÜVRheinland®**
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

 **TÜVRheinland**[®]
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

BIOSYSTEMS



BioSystems S.A., organizer of the training, CERTIFIES that

Mr. Nasedchin Alexandr

successfully participated in the service engineer's training
"Random Access Biochemistry Analyzer A15, A25"

May 18-22, Moscow 2009

Director of technical service department
Representative office "BioSystems S.A. Russia"

Sergey Vasiliyev



BIOSYSTEMS

BioSystems
REAGENTS & INSTRUMENTS

BioSystems S.A., organizer of the training, CERTIFIES that

Mr. Poiata Vitalie

successfully participated in the service engineer's training
"Random Access Biochemistry Analyzer A25 "

May 18-22, Moscow 2009

Director of technical service department
Representative office "BioSystems S.A." Russia

Sergey Vasiliyev





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 H11-800MA | DIRUI H12-800MA | |
| DIRUI H13-Cr | DIRUI H14-Ca | |
| DIRUI H13-Cr (H-800) | 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 9th, 2012
Changchun, China

Representative:

Yu Ge

Dirui Industrial Co., Ltd. 睿迪瑞医疗科技

于歌

股份有限公司



(place and date of issue)

(name and signature or equivalent marking of authorized person)

Authorization letter

To: Biosistem-mld SRL

Date: 29-07-2015

This is to certify that we, **DIRUI INDUSTRIAL CO., LTD** - China having registered offices at the below given address as a reputable manufacturer of Urine Reagent Strips, Urine Analyzers, Hematology analyzer and Chemistry Analyzer under ISO and CE condition to the international quality standards.

DIRUI INDUSTRIAL CO., LTD
95, Yunhe Street, New & High Tech Development Zone
Changchun 130012, China
Tel:0086-431-85100409
Fax:0086-431-85173354

Herein, we authorize,

Biosistem-mld SRL

as our **distributor** of Urine analyzers and consumables for their operation in Moldova. They are authorized to sell and service the products as well as to attend the local tenders with our products on Moldova market.

The commitment to supply our products to Biosistem-mld SRL will be valid until completion of the awarded contract.

For an on behalf of Dirui Industrial Co., LTD

Dima Ji
Sales Director
DIRUI INDUSTRIAL CO., LTD



2015.07.29

证书附件

标准 **ISO 9001:2015**
证书登记号码 **01 100 1832306**

号码	场地	认证范围
/01	(分证书) 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	体外诊断医疗器械的设计开发、生产和销售
/02	(分证书) 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：中华人民共和国吉林 省长春市高新技术产业开发区 宜居路 3333 号 邮编：130103	体外诊断医疗器械的设计开发、生产和销售

2021-04-19


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

页 1 / 1

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

所包括场地已列于证书附件上

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 2021-05-03 至 2024-05-02。**
此证书须经过符合要求的监督审核保持有效。
初次发证始于 2018 年
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306/01**

主证持有者: **迪瑞医疗科技股份有限公司**
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

场地: **(分证书) 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: 证书连同主证书 01 100 1832306 一起有效期从 2021-05-03 至 2024-05-02。

此证书须经过符合要求的监督审核保持有效。
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306/02**

主证持有者: **迪瑞医疗科技股份有限公司**
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

场地: **(分证书) 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: 中华人民共和国吉林省长春市
高新技术产业开发区宜居路 3333 号
邮编: 130103

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: 证书连同主证书 01 100 1832306 一起有效期从 2021-05-03 至 2024-05-02。

此证书须经过符合要求的监督审核保持有效。
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2015**

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

No.	Location	Scope
/01	c/o Dirui Industrial Co., Ltd. Unified Social Credit Code: 91220101605902656F Registration Address: 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P. R. China Operation Address: same as above	Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems
/02	c/o Dirui Industrial Co., Ltd. Unified Social Credit Code: 91220101605902656F Registration Address: 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P. R. China Operation Address: 3333 Yiju Street, New & High Tech. Development Zone, Changchun, 130103 Jilin, P. R. China	Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems

2021-04-19


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

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, 130012 Jilin, P. R. China
Operation Address: same as above

including the locations according to annex

Scope: Design and Development, Manufacture and Sales 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 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
First certification 2018
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2021-04-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

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

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

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

Scope: Design and Development, Manufacture and Sales 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 in conjunction with the main certificate 01
100 1832306 from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306/02**

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

Site: **c/o Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street,
New & High Tech. Development Zone,
Changchun, 130012 Jilin, P. R. China
Operation Address: 3333 Yiju Street,
New & High Tech. Development Zone,
Changchun, 130103 Jilin, P. R. China

Scope: Design and Development, Manufacture and Sales 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 in conjunction with the main certificate 01
100 1832306 from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2101045-1

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

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers and In-Vitro Diagnostic Test Kits used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers, Nucleic Acid Extraction Reagent and Specimen Receptacle for Clinical Laboratory Use.

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.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2101045-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Dirui Industrial Co., Ltd. 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P.R. China	Design and Development, Manufacture of In-Vitro Diagnostic Test Kits used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers, Nucleic Acid Extraction Reagent and Specimen Receptacle for Clinical Laboratory Use.

Report No.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2101045-1

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

The scope of certification also covers the following:

/02 c/o Dirui Industrial Co., Ltd.
3333 Yiju Street, New & High Tech.
Development Zone, Changchun,
130103 Jilin, P.R. China

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers for Clinical Laboratory Use.

Report No.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany