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ORDIN DE PLATA NR.: 1197                                TIP.DOC. 1 :
                                DATA EMITERII:25 februarie 2022 :
=====:
PLATITI: 24100-00          LEI: Douazeci si Patru Mii Una Suta :
lei 00 bani                                                         :
=====:
PLATITOR: (R) 'BIOSISTEM          CONTUL DE PLATI/CODUL IBAN :
MLD" SRL                      MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
                                :                               :
=====:
PRESTATORUL PLATITOR          CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau          :MOLDMD2X329:
=====:
BENEFICIAR (R) I.M.S.P. CE          CONTUL DE PLATI/CODUL IBAN :
NTRUL MEDICILOR DE FAMILIE MU MD09TRPCCW518430A00125AA :
NICIPAL BALTI                      CODUL FISCAL :1003602150710 / :
                                :                               :
=====:
PRESTATORUL BENEFICIAR          CODUL BANCII:
Ministerul Finantelor - Trezoreria de Stat          :TREZMD2X :
=====:
DESTINATIA PLATII:/P102/24100,00 Pentru : TIPUL TRANSFERULUI :
garantia pentru oferta la procedura de a:          NORMAL/URGENT :N:
chizi?ie publica nr. ocds-b3wdp1-MD-1642:          :
591795189 din 25.02.2022          :          :
                                :          :
                                :          L.S. :
=====:
                                : _____ :
                                CODUL TRANZACTIEI:101:          :
                                DATA PRIMIRII:25/02/2022          : SEMNATURILE          :
                                DATA EXECUTARII:          : EMITENTULUI          :
                                :-----:
CONducATOR:Web Poiata Vitalie          :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSq:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
-----:
                                (semnatura electronica)          :
CONTABIL-SEF:Web Nasedchin Alexandr          :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
-----:
L.S.          (semnatura electronica)          :
CONducATOR:          :
          (semnatura manuala)          :
CONTABIL-SEF:          :
          (semnatura manuala)          :
SEMnATURA PRESTATORUL          L.S.          :
-----:
MOTIVUL REFUZULUI          :          L.S.          :
-----:

```



# 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**

<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>

Cod Fiscal: 1010600028048; IBAN: MD95ML00000002251429243;  
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;  
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

## Scrisoare de informare

Prin prezenta, SRL „Biosistem mld”, va informeaza ca conform “*legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activității de întreprinzător*”, cu modificarile ulterior adoptate de parlamentul RM, *Importul, comercializarea, asistența tehnică si reparația dispozitivelor medicale* nu mai este activitate licentiata. Respectiv nu mai sunt eliberate licente pentru acest gen de activitate, iar licentele cu termenul de valabilitate expirat nu mai sunt prelungite.



Vitalie Poiata

L.Ș.

## ***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



## 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)



 **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](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**

To,  
Biosistem-mld SRL  
Albisoara 16/1 ap.7  
Chisinau, R. Moldova

26.02.2019

## MANUFACTURERS AUTHORIZATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** ("Mindray") manufacturer of Hematology analyzers, hereby authorize: **Biosistem-mld SRL**, with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to submit bids and subsequently negotiate and sign Contracts for reagents and consumables for all auto-hematology analyzers supplied by company **Biosistem-mld SRL**.

The authorization period is valid one year from issue date and automatically renewable if no termination letter is issued by either part.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of Product, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,



SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.  
4403055603013

Luan Haijiao

Deputy Manager of International Sales and Marketing System,  
Commonwealth of Independent States  
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

**SHENZHEN MINDRAY  
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,  
High-tech Industrial Park, Nanshan,  
Shenzhen 518057, P.R. China

Tel: +86 755 81888998

Fax: +86 755 26582680

Website: www.mindray.com

# 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.

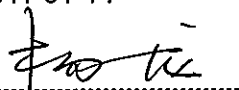
**Standards Applied:**

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

# 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-5000  
Including reagents as following:  
**M-52D DILUENT**  
**M-52DIFF LYSE**  
**M-52LH 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:** 2013-9-26

**Place, Date of Issue:** Shenzhen, 2013-9-26

**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-5150

Including reagents as following:

**M-52D DILUENT**  
**M-52DIFF LYSE**  
**M-52LH 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:** 2013-9-26

**Place, Date of Issue:** Shenzhen, 2013-9-26

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

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

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

## Applied Standards List

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

**BC-5150、BC-5000**

Including reagents as following:

**M-52D DILUENT**

**M-52DIFF LYSE**

**M-52LH LYSE**

**PROBE CLEANSER**

### Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer( labeling ) 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

## Declaration of Conformity V 1.0

IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and 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 62304:2008	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

AMZ MEDICAL



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**

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







# Certificate

No. Q5 044751 0164 Rev. 02

For the product(s)/product category (ies):

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 invitro diagnostic use,  
 Chemiluminescence Immunoassay Analyzer,  
 Flow Cytometer, (Auto) Sample Processing System,  
 Auto Slide Maker&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.

**LETTER OF AUTHORIZATION**

**Date:** September 10, 2019

**To whom it may concern,**

Diamond Diagnostics Inc., (hereinafter referred to as DD), having its registered office at 333 Fiske Street, Holliston, MA 01746, USA, Biosistem-mld SRL, with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to participate on any tender with the entire range of the SmartLyte and its consumables (hereinafter referred to as PRODUCTS) and as an official representative for registration of all our products in Moldova.

The Letter of Authorization is valid until 31<sup>st</sup> of December 2020, but may be freely withdrawn at any time.

Yours sincerely,

Eli Gallo  
*Regional Sales Manager*  
Diamond Diagnostics

**DIAMOND**  
**DIAGNOSTICS**  
Diamond Diagnostics, Inc.  
333 Fiske Street  
Holliston, MA 01746 USA  
508.429.0450 • Fax: 508.429.0452  
www.diamonddiagnostics.com

## DECLARATION OF CONFORMITY

**Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.**

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Unió 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et declare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics Inc. 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Européia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/EC Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنجاة المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعلیمة ان شركة دایموند دایاغونوستکس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che I prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispositivi medico-diagnostici in vitro.

**Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 產品(s) / Produto(s) / Продукт(ы) / المنتج(ق) / Prodott(i) ;**

**Model: Diamond Diagnostics SmartLyte/CareLyte/Gemlyte**

**Reagent & Controls:**

AV-BP5186D Fluid Pack	AV-BP0521D Deproteinizer	AV-BP1025D ISE Cleaning Solution
AV-BP0380D Electrode Conditioning Solution	AV-BP0344D Urine Diluent	

**Electrodes & Accessories:**

AV-BP0413D Na+ Electrode		
AV-BP0359D K+ Electrode	AV-BP5027D Peristaltic Pump Tubing	AV-BP5193D Pinch Valve Tubing Kit
AV-BP0570D Cl- Electrode	AV-BP5006D Sample Probe	AV-BP5014D Shutdown Kit
AV-BP0360D Ca++ Electrode	AV-BP5036D Sample Sensor	AV-BP5194D Startup Kit
AV-BP0962D Li+ Electrode	AV-BP5019D Reference Electrode Housing	AV-BP9043D Fillport Assembly
AV-BP5026D Reference Electrode	AV-BP5025D Printer Paper	

**(AR) Authorized Representative**

Diamond Diagnostics Kft.  
6 Óradna Street  
1044 Budapest Hungary  
Tel: + 3617872222 Fax: + 3617872255

**Authorized Officer:**

  
Kathy Fisher  
Global Quality Manager

**Date:** 30 April, 2018

**Manufacturer's name:** Diamond Diagnostics Inc. (USA)

**Manufacturer's address:** 333 Fiske Street  
Holliston, MA 01746 USA  
Tel: +1 (508) 429-0450  
Fax: +1 (508) 429-0452

**Quality Systems Registration**

ISO 13485:2016  
ISO 9001:2015

**Conformity Assessment Procedure**  
Annex III, Self-Declared







MAGYAR SZABVÁNYÜGYI TESTÜLET  
HUNGARIAN STANDARDS INSTITUTION

H-1082 Budapest, Horváth Mihály tér 1.

# TANÚSÍTÁSI OKIRAT CERTIFICATE

Tanúsítjuk, hogy a  
We certify that the Management System of  
***Diamond Diagnostics Inc. Magyarországi Fióktelepe***

H-1044 Budapest, Óradna utca 6.

Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:  
ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és  
klinikai diagnosztikai készülékek felújítása

meets the requirements of the standard for the following activities:  
the manufacture of blood electrolyte systems, consumables and  
re-manufacture of clinical diagnostic equipment

**MSZ EN ISO 13485:2016 (ISO 13485:2016)**

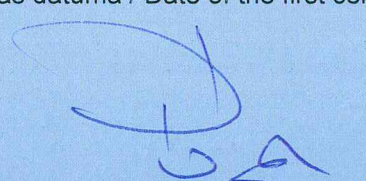


A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**  
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.  
This certificate is valid together with the maintenance decision annually issued by MSZT.

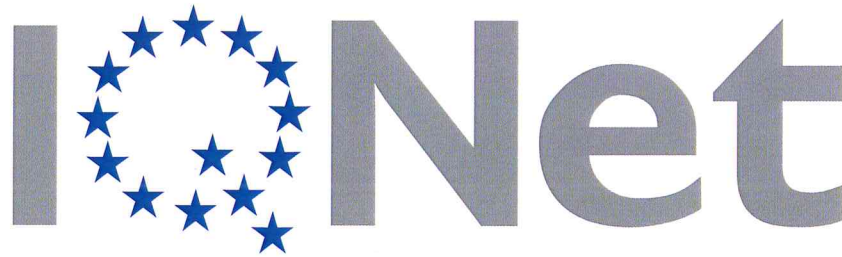
A tanúsítási okirat száma / Reg. number: **503/1342(2)**

Budapest, **2020. december 21.**

Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**

  
Pónyai György  
ügyvezető igazgató





THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

MSZT has issued an IQNet recognized certificate that the organization:

**Diamond Diagnostics Inc.**  
**Magyarországi Fióktelepe**

H-1044 Budapest, Óradna utca 6.

Certified headquarters: H-1044 Budapest, Óradna utca 6.

has implemented and maintains a

**Quality Management System**

for the following scope

**the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment**

which fulfils the requirements of the following standard:

**ISO 13485:2016**

Issued on: **21-12-2020**

First issued on: **26-06-2014**

Expires on: **21-06-2023**

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document*

**Registration Number: HU-MSZT-503/1342(2)-1262(2)**

Alex Stoichitoiu  
President of IQNet

György Pónyai  
General Director of MSZT



**IQNet Partners\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group  
USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



MAGYAR SZABVÁNYÜGYI TESTÜLET  
HUNGARIAN STANDARDS INSTITUTION  
H-1082 Budapest, Horváth Mihály tér 1.

# TANÚSÍTÁSI OKIRAT CERTIFICATE

Tanúsítjuk, hogy a  
We certify that the Management System of  
***Diamond Diagnostics Inc. Magyarországi Fióktelepe***  
H-1044 Budapest, Óradna utca 6.  
Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:  
**ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és  
klinikai diagnosztikai készülékek felújítása**

meets the requirements of the standard for the following activities:  
**the manufacture of blood electrolyte systems, consumables and re-manufacture of  
clinical diagnostic equipment**

**MSZ EN ISO 9001:2015 (ISO 9001:2015)**

A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**  
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.  
This certificate is valid together with the maintenance decision annually issued by MSZT.

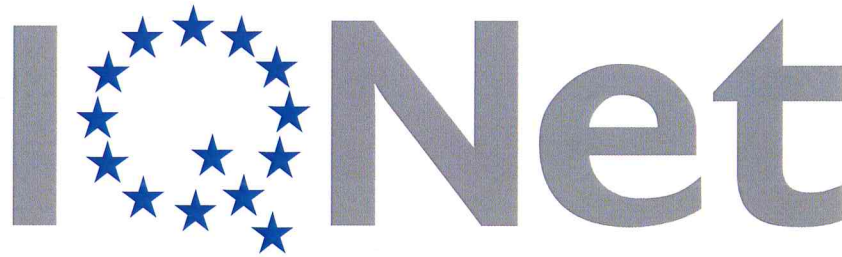
A tanúsítási okirat száma / Reg. number: **503/1341(2)**

Budapest, **2020. december 21.**

Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**

Pónyai György  
ügyvezető igazgató





THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*MSZT has issued an IQNet recognized certificate that the organization:*

***Diamond Diagnostics Inc.  
Magyarországi Fióktelepe***

**H-1044 Budapest, Óradna utca 6.**

**Certified headquarters: H-1044 Budapest, Óradna utca 6.**

has implemented and maintains a

***Quality Management System***

for the following scope

**the manufacture of blood electrolyte systems, consumables and  
re-manufacture of clinical diagnostic equipment**

which fulfils the requirements of the following standard:

**ISO 9001:2015**

Issued on: **21-12-2020**

First issued on: **26-06-2014**

Expires on: **21-06-2023**

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document*

**Registration Number: HU-MSZT-503/1341(2)-1261(2)**

*Alex Stoichitoiu*  
President of IQNet

*György Pónyai*  
General Director of MSZT



**IQNet Partners\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group  
USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)