

ORDIN DE PLATA NR.: 2650 TIP.DOC. 1 :
DATA EMITERII:joi, 22 februarie :
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PLATITI: 1500-00 LEI: Una Mie Cinci Sute 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. SP CONTUL DE PLATI/CODUL IBAN :
ITALUL CLINIC DE PSIHIATRIE MD96VI022511700000037MDL :
CODUL FISCAL :1003600150554 / :
: :
: :
=====

PRESTATORUL BENEFICIAR CODUL BANCII: :
B.C."VICTORIABANK"S.A. :VICBMD2X :
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DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizi?ie public: NORMAL/URGENT :N: :
a nr. ocds-b3wdp1-MD-1707896818901 din 2: :
4.02.2024 : :
: :
: : L.S. :
=====

CODUL TRANZACTIEI:001: :
DATA PRIMIRII:22/02/2024 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----

CONDUCATOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB: :
DQEHAaACCBGwwggRoMIIDUKADAgECAhNHAAEIdi65avx+fxSlAAAAAQOLMA0GCSq: :
SIB3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4: :
DTI0MDEyNTEzMzYwXDTI0MDEyNTEyNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRA: :
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml :
: :
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3: :
DQEHAaACCBHAWggRsMIIDVKADAgECAhNHAAEIdijjVd7aJ5r0rAAAAAQOKMA0GCSqG: :
SIB3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X: :
DTI0MDEyNTEyNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRAw: :
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
: :
L.S. (semnatura electronica) :
CONDUCATOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
: :
: :
MOTIVUL REFUZULUI : L.S. :



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



MCabinet
PORTALUL GUVERNAMENTAL
AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
Nº

1403048

Din
Ot

13.02.2024 14:03



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Denumirea

Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD



ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI

INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ
ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ
СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

28.02.2024 14:03



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствии со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la 13.02.2024 14:03

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такую же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Государственной Службой Электронной Подписью (msign.gov.md)



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, 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 în moneda națională 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





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei,**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

- 1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494

Lista fondatorilor Biosistem-mld SRL

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

Annex to certificate

Standard **ISO 9001:2015**

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

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

2022-12-15



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

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

Certificate Holder: **BIOSYSTEMS S.A.**

Costa Brava 30
08030 Barcelona
Spain

including the locations according to annex

Scope:

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

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

Reagent labelling and assembly.

Storage of raw materials for instruments, instruments and reagents for:

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

Dispatched or stored product.

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

Validity:

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

2022-12-15



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

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

Registration No.: SX 1695779-1

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

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

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

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



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



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

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1695779-1

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

The scope of certification includes the following additional sites:

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

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

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)	Metanephtrines
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-MPO Antibodies
Anti-Annexin V IgG/IgM (ANX)	Anti-Nucleosome Antibodies (NCL)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)	Anti-Phospholipid IgG/IgM (APLA)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)	Anti-PR3 Antibodies
Anti-Centromere B Antibodies (CENP-B)	Anti-Ribosomal P Antibodies (Rib P)
Anti-Citrullinated Protein Antibodies (ACPA)	Anti-Scl70 Antibodies
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)	Anti-Sm Antibodies
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)	Anti-Sm/RNP Antibodies
Anti-dsDNA Antibodies	Anti-SSA (Ro) Antibodies
Anti-GBM Antibodies - EIA (GBM)	Anti-SSB (La) Antibodies
Anti-Gliadin Antibodies (AGA-IgG/IgA)	Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Histones Antibodies (HIST)	Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-Insulin Antibodies (INS)	Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-Jo1 Antibodies	Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
Anti-M2 Antibodies (M2)	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

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.

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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



Product Service

Certificate

No. Q5 044751 0164 Rev. 02

Holder of Certificate: **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: **Design and development, production and distribution of Active medical devices (intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro diagnostic instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits (intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH2005501

Valid from: 2020-09-01
Valid until: 2023-08-31

Date, 2020-07-24

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 044751 0164 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

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.



BIO GROUP – MEDICAL SYSTEM Srl
Strumentazione e Diagnostici
Loc. Campiano, 9/B – 47867 Talamello (RN)
e.mail: info@biogroupmedicalsystem.com
Tel. +39 0541 920686
Fax +39 0541 922130

Declaration of conformity certificate

We: Bio Group Medical System Srl Loc. Campiano 9/B, Talamello (RN) 47867 Italy
Ensure and declare with sole responsibility that the products:

Internal code: MSEQUALITYCH-MSEQSCH12-MSEQSCH4 EDMA Code: 38220000	Commercial name: QS Clinical Chemistry First lot introduced in market: 112-NB
Internal code: MSEQUALITYPS EDMA Code: 38220000	Commercial name: QS Specific Protein First lot introduced in market: 220-NB
Internal code: MSEQUALITYEF EDMA Code: 38220000	Commercial name: QS Electrophoresis First lot introduced in market: 220-NB
Internal code: MSEQUALITYE8-MSEQSE12 EDMA Code: 30021095	Commercial name: QS Hematology First lot introduced in market: 2020-EN
Internal code: MSEQUALITYC-MSEQSC12-MSEQSC4 EDMA Code: 38220000	Commercial name: QS Coagulation First lot introduced in market: 084
Internal code: MSEQUALITYI-MSEQSI12-MSEQSI4 EDMA Code: 38220000	Commercial name: QS Immunology First lot introduced in market: 360
Internal code: MSEQUALITYB EDMA Code: 38220000	Commercial name: QS Bacteriology First lot introduced in market: 326
Internal code: MSEQUALITYS EDMA Code: 38220000	Commercial name: QS Serology First lot introduced in market: 1020-SI
Internal code: MSEQUALITYU EDMA Code: 38220000	Commercial name: QS Urine First lot introduced in market: 002-U
Internal Code: MSEQUALITYH-MSEQSHB12 EDMA Code: 38220000	Commercial name: QS HBA1C First lot introduced in market: 001-H
Internal Code: MSEQUALITYD EDMA Code: 38220000	Commercial name: QS Drug of Abuse First lot introduced in market: 330-D
Internal Code: MSEQUALITYSO EDMA Code: 38220000	Commercial name: QS FOB First lot introduced in market: 110-F
Internal Code: MSEQUALITYESR EDMA Code: 30021095	Commercial name: QS ESR First lot introduced in market: 001-V
Internal Code: MSEQUALITYCM EDMA Code: 38220000	Commercial Name: QS Cardiac Marker First lot introduced in market: 201-C

meet the provisions of Council Directive 98/79/CE, annex I, as expected according to Council Directive 98/79/CE, annex III, concerning In Vitro Medical-Diagnostic Devices, which apply to us.

To this purpose, we guarantee and declare, on our own responsibility, what follows:

- ◆ Subsequent lots will be consistent with technical specification of the first lot. This conformity will be attested on the quality control certificate.
- ◆ The specified item satisfy the all dispositions applicable of Directive 98/79/CE
- ◆ We undertake in storing and placing to the competent Authority disposal the technical dossier of the product, as required by Council Directive 98/79/CE, annex III, as well as the production and control registrations for a period of at least 5 years after the last production date of the last lot.
- ◆ The specified device is designed, manufactured, and commercialized with date of first release not preceding the present one.

The present conformity declaration has validity of a maximum of 5 years.

Moreover, the manufacturer declare to have established and to maintain an appropriate procedure to guarantee the post-sale surveillance, as requested by Council Directive 98/79/CE.



Talamello, January the 29th, 2019

Cap. Soc. € 75.300,00 i.v. – Reg. Trib. Pesaro 7163 C.C.I.A.A. 98204 – P.I.A.C. Fisc. 0096170419

BIO GROUP
MEDICAL SYSTEM SRL
Loc. Campiano 9/B – 47867 Talamello (RN)
P.I.A.C. Fisc. 0096170419



CERTIFICATO DI ACCREDITAMENTO Accreditation Certificate

ACCREDITAMENTO N.
ACCREDITATION N.

0017P REV. 00

EMESSO DA
ISSUED BY

DIPARTIMENTO LABORATORI DI PROVA

SI DICHIARA CHE
WE DECLARE THAT

BIO-GROUP MEDICAL SYSTEM S.r.l.

Sede/Headquarters:

- Loc. Campiano 9/b - 47867 Talamello RN

È CONFORME AI REQUISITI
DELLA NORMA

UNI CEI EN ISO/IEC 17043:2010

MEETS THE REQUIREMENTS
OF THE STANDARD

ISO/IEC 17043:2010

QUALE

Organizzatori di prove valutative interlaboratorio

AS

Proficiency Testing Provider

Data di 1^a emissione
1st issue date
14-11-2018

Data di modifica
Modification date
14-11-2018

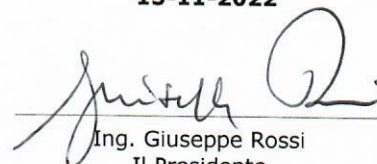
Data di scadenza
Expiring date
13-11-2022



Dott.ssa Silvia Tramontin
Il Direttore di Dipartimento
The Department Director



Dott. Filippo Trifiletti
Il Direttore Generale
The General Director



Ing. Giuseppe Rossi
Il Presidente
The President

L'accREDITAMENTO attesta la competenza tecnica dell'Organizzazione relativamente al campo di accREDITAMENTO riportato nell'Elenco Schemi allegato al presente certificato di accREDITAMENTO.

Il presente certificato non è da ritenersi valido se non accompagnato dagli Elenchi Schemi, che possono variare nel tempo.

La validità dell'accREDITAMENTO può essere verificata sul sito web (www.accredia.it) o richiesta al Dipartimento di competenza.

The accreditation certifies the technical competence of the organisation limited to the scope detailed in the attached Enclosure. The present certificate is valid only if associated to the annexed schedule, that may vary in the time.

Confirmation of the validity of accreditation can be verified on website www.accredia.it or by contacting the relevant Department.