Digitally signed by Poiata Vitalie
Date: 2019.12.18 13:05:29 EET
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII **Nr.** 044322

Denumirea autorității de licențiere	**Camera de Licențiere**
Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență	**Societatea cu Răspundere Limitată "BIOSISTEM MLD"** mun.Chișinău, str. Albișoara, 16/1, ap. 7
Data și numărul certificatului de înregistrare de stat a titularului de licență	12.08.2010 MD 0101250
Numărul de înregistrare a întreprinderii sau IDNO	1010600028048
Codul fiscal	
Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența	*** Importul, comercializarea, asistența tehnică și reparația dispozitivelor medicale ***
Data eliberării licenței	4 octombrie 2010
Reperfectată: 1)19.10.2012; 2)14.05.2014	
Valabilă pînă la	4 octombrie 2015
Prelungită pînă la: 03.10.2020	

Semnătura conducătorului autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC

L.Ș.

Notă: Licența este valabilă numai cu anexa autentificată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.

BC "MOLDINDCONBANK" S.A.
Filiala "Invest"

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000002251429243**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

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

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

„CAMERA ÎNREGISTRĂRII DE STAT" Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. **14419** din **11.07.2016**

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**
Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**
Forma juridică de organizare: **Societate cu Răspundere Limitată.**
Numărul de identificare de stat și codul fiscal: **1010600028048.**
Data înregistrării de stat: **12.08.2010.**
Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**
Modul de constituire: **nou creată.**
Obiectul principal de activitate:
1 Activitatea farmaceutică;
2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;
3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;
4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;
5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;
6 Consultații în domeniul sistemelor de calcul.
Capitalul social: **5400** lei.
Administrator: POIATA VITALIE, IDNP 0983103892591,
Asociați:
1. POIATA VITALIE , IDNP 0983103892591
cota 1803.60 lei, ce constituie 33,4 %
2. NASEDCHIN ALEXANDR , IDNP 2002001070747
cota 1798.20 lei, ce constituie 33,3 %
3. KOJEVNIKOV DMITRII , IDNP 0972305012362
cota 1798.20 lei, ce constituie 33,3 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

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

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A1947807 **din** / от 09.12.2019

1. Destinația / Назначение

Pentru participarea 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 24.12.2019

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

Şef DDF Rîşcani
a DGAF mun.Chişinău
Funcția/Должность

Semnătura/Подпись

Ana STOICOV
Numele și prenumele/Фамилия и имя

L.Ş/ М.П.

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

MINISTERUL FINANȚELOR AL REPUBLICII MOLDOVA
IDNO 1006601001182
SERVICIUL FISCAL DE STAT
S7

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 09.12.2019 ora 15:55:24 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,29)

ORDIN DE PLATA NR.: 497 TIP.DOC. 1

DATA EMITERII:17 decembrie 2019

PLATITI: 6000-00 LEI: Sase Mii lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL

CONTUL DE PLATI/CODUL IBAN
MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) IMSP CS So roca

CONTUL DE PLATI/CODUL IBAN
MD26VI0000000225100 62MDL
CODUL FISCAL :1007607008571 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A. fil.nr.6 Soroca

CODUL BANCII:
:VICBMD2X808:

DESTINATIA PLATII:Pentru garantia pentru: oferta la licitatia publica nr ocds-b3w: dp1-MD-1575474249366 din 31.12.2019

TIPUL TRANSFERULUI : NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:17/12/2019

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxFzA

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT

L.S. (semnatura electronica)

CONDUCATOR: (semnatura manuala)

CONTABIL-SEF: (semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

BioSystems
REAGENTS & INSTRUMENTS

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

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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

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

(including the locations according to annex)

Scope: Design, development, manufacture, distribution, installation and servicing of:
- Instruments and reagents for clinical diagnostic.
- Instruments and reagents for agro-alimentary analysis.
Distribution and servicing of instruments and reagents 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 2017-12-13 until 2019-12-18.
First certification 1996

2017-12-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

No.	Location	Scope
/01	**BIOSYSTEMS, S.A.** Pl. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labelling and assembling of reagents. Warehousing and shipment of: -Instruments and Reagents for clinical diagnostic. -Instruments and Reagents for agro-alimentary analysis. -Instruments and Reagents for veterinary diagnosis.

2017-12-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

TÜVRheinland®

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:	2017-11-28
Certificate Registration No.:	SX 60124804 0001
An audit was performed. Report No.:	28300434 002
This Certificate is valid until:	2019-12-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-11-28

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60124804 0001
Report No.: 28300434 002

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 (Barcelona)
Spain

Scope:
Labelling and Assembling of reagents and Warehousing and Shipment of instruments and reagents for clinical diagnostic

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-11-28

X. Ren

TÜRKLAB
let us diagnose

FACTORY
ITOB 10031 Sk. No:15 Menderes – Izmir / TURKEY
www.turklab.com.tr

HEAD OFFICE
Sasali Merkez Mah. Doğa Dostları Sitesi 131. Sok. No:2/5 Çiğli - İzmir
Tel: +90 232 376 80 81 Fax: +90 232 376 80 40

21.08.2016
Izmir / Turkey

DECLARATION FOR THE ISSUANCE OF QUALITY CERTIFICATES

To Whom It May Concern,

According to IVD 98/79/EC directive,

FOR ANNEX II LIST A which includes HIV, Hepatitis B and Hepatitis C tests; the Notified Body must verify that the product meets the Common Technical Specification (CTS) and must release each batch of product before it is placed on the European market. The batch release often requires testing. These have EC Design Examination certificates by the notified body.

FOR ANNEX III which includes all other tests for Professional use; the manufacturer prepares a declaration of conformity in a similar way to the general devices.

For the above mentioned reason, we hereby declare that we provide CE Certificate for only the Hepatitis B, Hepatitis C and HIV tests for Professional use. For the group of other Professional tests; it is enough to present a self-Declaration of Conformity to the EU standards.

Cordially,

TURKLAB TIBBİ MALZEMELER SAN TİC A.Ş

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-56/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 45/2016
Contract No. MD-18/2016

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-57/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices, List A:

HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 45/2016
Contract No. MD-18/2016

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-52/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 43/2016
Contract No. MD-16/2016

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-53/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices, List A:

Anti-HCV Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 43/2016
Contract No. MD-16/2016

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-54/2016

EC Design-Examination

Directive 98/79/ECon in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

Anti-HBs Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 44/2016
Contract No. MD-17/2016

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-55/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices, List A:

Anti-HBs Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 44/2016
Contract No. MD-17/2016

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-58/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

Anti - HIV 1/2 Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 46/2016
Contract No. MD-19/2016

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-59/2016

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

for the design, manufacture and final inspection of in vitro diagnostic medical devices,
List A:

Anti - HIV 1/2 Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 46/2016
Contract No. MD-19/2016

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-51/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device for self-testing:

hCG Pregnancy Test
Brands: Rapidan Nova®, Rapidan Optima®, Info®, Toyo®, Rapidan Tester®, Rapidan Compact®, Labmen®

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

was examined by PCBC according to Annex III p. 6 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**

Anna Wyroba
Vice President of PCBC

CE 1434

PCBC Notified Body
23A, Klobucka Str., PL-02-699 Warsaw

Application No. 42/2016
Contract No. MD-15/2016

Module A1

CERTIFICATE

No. J - 2670/2/2018

This is to certify that:

TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.

Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5 35621 Çiğli, İzmir, Turkey

Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro diagnostic medical devices intended for self-testing and professional use, ECG electrodes and antibiotic susceptibility discs

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 24.08.2018 to 21.12.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania

AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Wyroba, M.Sc.
Vice President

Certificate No. **J - 2670/2/2018**
Issued under the Contract No. 2897/JM/3/2017
Date of certification decision: 24.08.2018
Bears the PCBC hologram.
Warsaw, 24.08.2018

CERTIFICATE

No. M - 56/2/2018

This is to certify that:

TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.

Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5 35621 Çiğli, İzmir, Turkey

Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro diagnostic medical devices intended for self-testing and professional use, ECG electrodes and antibiotic susceptibility discs

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 24.08.2018 to 21.12.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania

AC 019
QMS

IAF Member of Multilateral Recognition Arrangement

Anna Wyroba, M.Sc.
Vice President

Certificate No. **M - 56/2/2018**
Issued under the Contract No. 2897/JM/3/2017
Date of certification decision: 24.08.2018
Bears the PCBC hologram.
Warsaw, 24.08.2018

CE Declaration of Conformity CE

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 M10** **DIRUI H10-800**
DIRUI H11 **DIRUI H11-MA** **DIRUI H11-800**
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 Directive98/79/EC, Annex III.

Valid Since
May 9th, 2012
Changchun, China

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

(place and date of issue)

(name and signature or equivalent marking of authorized person)

认证证书

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

证书持有者：

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

认证范围：

体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期：

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

2018-05-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Certificate

Standard **ISO 9001:2015**

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

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

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

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

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

2018-05-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

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

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-06-26

X. Ren

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60127937 0001
Report No.: 15047317 007

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

Scope:

Products:

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

Site included:

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

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

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-06-26

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 03 44751 089

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:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

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.: SH1705528

Valid from: 2017-09-01
Valid until: 2020-08-31

0405276870507S

Date, 2017-06-28

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE
No. Q5 17 03 44751 089

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.
Bldg 9-13, Baiwangxin High-Tech Industrial Park, Baimang, Xili Town, Nanshan, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

**Shenzhen Mindray Biomedical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attachment for Certificate No. Q5 17 03 44751 089
Dated: 2017-06-28

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, Wearable ECG Recorder,
Anesthesia Machine and Accessories, Ventilator,
Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System,
Ultrasonic Diagnostic Equipment and Accessories,
Digital Radiography System, Radiography System, Magnetic Resonance Imaging System
Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader,
Microplate Washer for invitro diagnostic use, Chemiluminescence Immunossay 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 Immunoassav 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

Munich, CRT, 2017-06-28

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

No. QS5 17 07 44751 097

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:

TÜV SÜD ISO 9001

Scope of Certificate:

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, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay 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,

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.: M2606
Effective Date: 2017-07-01
Expiry Date: 2020-06-30

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

040527682186 43

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®

SCC Accredited CB-MS OCSM Accrédité CCN

UCB_F_12.04 2012-02

ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan, 518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay 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 Immunoassav 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

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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Baimang, Xili Town
Nanshan, 518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Manufacturing of 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, Wearable ECG Recorder, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System. Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Effective Date: **2017-07-01**
Expiry Date: **2020-06-30**

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

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No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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Guangming District
518016 Shenzhen
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