



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. Московей, 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 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

MD 0101250





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:

We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

Classification: The device not in IVDD annex II and not for self testing/performance evaluation

Product Category(ies): Clinical Chemistry Analyzer, Hematology Analyzer, Microplate washer, Microplate reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Reagents for Chemiluminescence Immunoassay Analyzer, Urinalysis reagent strips.

Products: Attachment I

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

We hereby certify that the forgoing is a true and accurate statement.

Place, Date Of Issue : Shenzhen, **2016-09-01**



Signatory name: Chuanbin Tan

signatory title: Technical Regulation Manager

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

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ATTACHMENT I

Product Name	Product Model	Accessories
Hematology Analyzer	BC-2300、 BC-2100	M-23CFL LYSE M-23D DILUENT M-23E E-Z CLEANSER M-23P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-1800、 BC-1900、 BC-2900	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator BC-3D Hematology Control SC-CAL PLUS Hematology Calibrator
Auto Hematology Analyzer	BC-3000 Plus	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3200、 BC-3200CT	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-5500、	M-50D DILUENT

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	BC-5200	M-50LH LYSE M-50LEO(I)LYSE M-50LEO(II)LYSE M-50LBA LYSE M-50 CLEANSER M-50P PROBE CLEANSER BC-5D Hematology Control CBC-5DMR Hematology Control SC-CAL PLUS Hematology Calibrator S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5300、 BC-5100	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5380、 BC-5180	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-2800、 BC-2600	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology

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		Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300、 BC-3300CT、 BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800、 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-6600、 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator BR60 Hematology Control
Auto Hematology Analyzer	BC-5310	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control

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Auto Hematology Analyzer	BC-5390	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5150、 BC-5000、 HM-500X	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator
Urine Analyzer	UA-66、 UA-600、 UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、 BC-21s、 BC-30s、 BC-31s、 HM-200X	M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5390 CRP BC-5180 CRP	M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
Auto Sample Processing System	CAL 8000	/
Auto Slide Maker & Stainer	SC-120	M-68DS DILUENT PROBE CLEANSE
Automated Glycohemoglobin Analyzer	H50 H50P	Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control

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		Hemoglobin A1c Calibrator
Flow Cytometer	BriCyte E6	Sheath Fluid Cleaning Solution
Lysing Solution	/	/
CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent HLA-B27 Reagent	/	/
Laboratory Data Management Software	/	/
Mindray labXpert Software	/	/
Specific Protein Analyzer	CRP-M100	M-68DS Diluent LC Lyse CRP Cleanser Probe Cleanser
Auto Hematology Analyzer	BC-5120 BC-5130 BC-5140	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER
Chemistry Analyzer	BS-300、BS-320	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit
Chemistry Analyzer	BS-400、BS-420	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette

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		Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	Perfect plus	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	BS-380、BS-390	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit
Chemistry Analyzer	BS-350、BS-330	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode

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		Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、 BS-180	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200、BS-220	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200E/BS-220E BS-330E/BS-350E	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode

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		Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Microplate reader	MR-96A	/
Microplate washer	MW-12A	/
Chemistry Analyzer	BS-800、BS-820、 BS-800M、 BS-820M、 BS-1800、BS-1800 plus	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System (RMS)
Chemistry Analyzer	BS-2000、 BS-2000M、 BS-2200、 BS-2200M	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System (RMS)

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Chemistry Analyzer	BS-600、BS-620	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit External vacuum pump unit
Chemistry Analyzer	BS-480、BS-490	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Built-in sample/reagent bar code reader Remote management system (RMS) Water supply module External air pump
Chemistry Analyzer	BS-430、BS-450、 BS-460	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode

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		Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit Probe clog detection module
Chemistry Analyzer	BS-230、BS-240	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code reader(optional)
Chemiluminescence Immunoassay Analyzer	CL-2000i、 CL-2200i	Hand-held bar code reader External vacuum pump Reaction cuvette Waste Bin
Chemiluminescence Immunoassay Analyzer	CL-1000i、 CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. waste container
α -Amylase (α -AMY) Kit (IFCC Method)	/	/

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Aspartate Aminotransferase (AST) Kit (IFCC Method)	/	/
Gamma-Glutamyltransferase (GGT) Kit (Szasz Method /IFCC stand.)	/	/
Lactate Dehydrogenase (LDH) Kit (IFCC Method)	/	/
Alanine Aminotransferase (ALT) Kit (IFCC Method)	/	/
C-Reactive Protein Kit(Turbidimetry Method)	/	/
Apolipoprotein B Kit (Turbidimetry Method)	/	/
Apolipoprotein A1 Kit (Turbidimetry Method)	/	/
Triglycerides Kit(GPO-POD Method)	/	/
Bilirubin Total Kit(DSA Method)	/	/
Creatinine Kit(Modified Jaffe Method)	/	/
Albumin Kit(Bromcresol Green Method)	/	/
Bilirubin Direct Kit(DSA Method)	/	/
Total Protein Kit(Biuret Method)	/	/
Magnesium Kit(Xylidyl Blue Method)	/	/
α -Hydroxybutyrate Dehydrogenase Kit(DGKC Method)	/	/
Total Cholesterol kit(CHOD-POD Method)	/	/
Alkaline Phosphatase Kit(IFCC Modified Method)	/	/
Urea Kit(Urease-GLDH,UV Method)	/	/
Uric Acid Kit(Uricase-peroxidase Method)	/	/

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Glucose Kit (GOD-POD Method)	/	/
Phosphorus Kit(Phosphomolybdate Method)	/	/
Calcium Kit(Arsenazo III Method)	/	/
Lipoprotein(a) Kit(Turbidimetry Method)	/	/
Complement C3 Kit(Turbidimetry Method)	/	/
Complement C4 Kit(Turbidimetry Method)	/	/
Immunoglobulin M Kit(Turbidimetry Method)	/	/
Immunoglobulin G Kit(Turbidimetry Method)	/	/
Prealbumin Kit(Turibidimetry Method)	/	/
Glucose Kit (HK Method)	/	/
Immunoglobulin A Kit(Turbidimetry Method)	/	/
Bilirubin Total Kit(VOX Method)	/	/
Creatine Kinase Kit(IFCC Method)	/	/
Total Bile Acids Kit(Enzymatic Cycling assay)	/	/
Creatinine Kit(Sarcosine Oxidase Method)	/	/
HDL-Cholesterol kit(Direct Method)	/	/
Bilirubin Direct Kit(VOX Method)	/	/
LDL-Cholesterol Kit(Direct Method)	/	/
Creatine Kinase-MB Kit(IFCC Method)	/	/

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HDL&LDL Cholesterol Control P	/	/
Prealbumin Control N&P	/	/
Lipids Calibrator	/	/
Specific Proteins Calibrator	/	/
Multi Sera Calibrator	/	/
CK-MB Calibrator	/	/
Lipoprotein(a) Calibrator	/	/
Multi Control Sera N Multi Control Sera P	/	/
Prealbumin Calibrator	/	/
Lipoprotein(a) Control N&P	/	/
Lipids Control N Lipids Control P	/	/
CK-MB Control N CK-MB Control p	/	/
Specific Proteins Control N Specific Proteins Control P	/	/
Cholinesterase(CHE) Kit (DGKC Method)	/	/
Carbon Dioxide (CO2) Kit (Enzymic Method)	/	/
Iron (Fe) Kit (Colorimetric Assay)	/	/
Fructosamine (FUN) Kit(Colorimetric Assay)	/	/
Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method	/	/
Homocysteine Kit(Enzymatic Assay Method)	/	/
Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/

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Lipase Kit(Enzymatic Colorimetric Assay Method)	/	/
Hemoglobin A1c Kit (Enzymatic Assay Method)	/	/
Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method)	/	/
Microalbumin (MALB) Kit	/	/
Ferritin (FER) Kit	/	/
Transferrin (TRF) Kit	/	/
TRF Calibrator	/	/
TRF Control	/	/
FER Calibrator	/	/
Multimun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
α -L-Fucosidase Kit (CNPF method)	/	/
5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
β 2-Microglobulin Kit (Turbidimetry Method)	/	/
5'-NT Calibrator	/	/
5'-NT Control	/	/
ADA Control	/	/
ADA Calibrator	/	/
AFU Control	/	/
ASO Calibrator	/	/
CysC Calibrator	/	/

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CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
β2-MG Calibrator	/	/
β2-MG Control	/	/
Free Triiodothyronine (CLIA)	/	/
Free Thyroxine (CLIA)	/	/
Total Triiodothyronine (CLIA)	/	/
Total Thyroxine (CLIA)	/	/
Thyroid-stimulating Hormone (CLIA)	/	/
Follicle Stimulating Hormone (CLIA)	/	/
Luteinizing Hormone (CLIA)	/	/
Prolactin (CLIA)	/	/
Estradiol (CLIA)	/	/
Estriol (CLIA)	/	/
Testosterone (CLIA)	/	/
Progesterone (CLIA)	/	/
Total β Human Chorionic Gonadotropin (CLIA)	/	/
Free T3 Calibrators	/	/
Free T4 Calibrators	/	/
Total T3 Calibrators	/	/
Total T4 Calibrators	/	/
TSH Calibrators	/	/
FSH Calibrators	/	/
LH Calibrators	/	/
Prolactin Calibrators	/	/
Estradiol Calibrators	/	/
Estriol Calibrators	/	/
Testosterone Calibrators	/	/
Progesterone Calibrators	/	/
Total β HCG Calibrators	/	/

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Thyroid Function Multi Control	/	/
Reproductive Multi Control	/	/
Carcinoembryonic Antigen (CLIA)	/	/
Alpha-fetoprotein (CLIA)	/	/
Cancer Antigen 125 (CLIA)	/	/
Cancer Antigen 15-3 (CLIA)	/	/
Carbohydrate Antigen 19-9 (CLIA)	/	/
CEA Calibrators	/	/
AFP Calibrators	/	/
CA125 Calibrators	/	/
CA15-3 Calibrators	/	/
CA19-9 Calibrators	/	/
Ferritin (CLIA)	/	/
Ferritin Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" (ASO) Kit (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF triple Control	/	/
Cystatin C (CysC) Kit (Latex Immunoturbidimetric Method)	/	/
Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein (FR-CRP) Kit(Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor (RF) Kit(Immunoturbidimetric Method)	/	/
Rheumatoid Factor Calibrator	/	/
β 2-Microglobulin (β 2-MG) Kit (Latex Immunoturbidimetric Method)	/	/
β 2-Microglobulin Control	/	/
β 2-Microglobulin Calibrator (for Serum)	/	/
β 2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/

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Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method)	/	/
Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Immunoglobulin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
β -Hydroxybutyrate (β -HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
HbA1c control N	/	/
HbA1c control P	/	/
Rheumatism Control N	/	/
Rheumatism Control P	/	/
HCY Control N	/	/
HCY Control P	/	/
FUN Control P	/	/
CO2 Control N	/	/
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/
MYO Calibrator	/	/
IgE Calibrator	/	/
β -HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
β -HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I(CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide(CLIA)	/	/
BNP Calibrators	/	/
Myoglobin(CLIA)	/	/
MYO Calibrators	/	/

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Creatine kinase MB(CLIA)	/	/
CK-MB Calibrators	/	/
Thyroglobulin(CLIA)	/	/
Thyroglobulin Calibrators	/	/
Antibody to thyroglobulin(CLIA)	/	/
Anti-Tg Calibrators	/	/
Antibody to thyroid peroxidase(CLIA)	/	/
Anti-TPO Calibrators	/	/
Insulin(CLIA)	/	/
Insulin Calibrators	/	/
C-Peptide(CLIA)	/	/
C-Peptide Calibrators	/	/
Cortisol(CLIA)	/	/
Cortisol Calibrators	/	/
Dehydroepiandrosterone sulfate(CLIA)	/	/
DHEA-S Calibrators	/	/
Adrenocorticotrophic hormone(CLIA)	/	/
ACTH Calibrators	/	/
Cardiac Marker Multi Control	/	/
Thyroid Function Multi Control	/	/
Immunoassay Multi Control	/	/
ACTH Control	/	/
Anti-thyroid Antibodies Control	/	/
System Detection Solution	/	/
System Wash Solution	/	/
ClinChem Multi Control (level 1)	/	/
ClinChem Multi Control (level 2)		
Sample Diluent	/	/
HCY Control	/	/
Homocysteine (HCY) Kit (Enzymatic Cycling Method)	/	/
Total Protein in Urine/CSF(TPUC) Kit (Pyrogallol Red-Molybdate Method)	/	/
TPUC Control	/	/
25-OH-Vitamin D Total (CLIA)	/	/

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25-OH-Vitamin D Total Calibrators	/	/
Parathyroid hormone (CLIA)	/	/
PTH Calibrators	/	/
Calcitonin (CLIA)	/	/
Calcitonin Calibrators	/	/
Folate(CLIA)	/	/
Folate Calibrators	/	/
Vitamin B12(CLIA)	/	/
Vitamin B12 Calibrators	/	/
Metabolic Multi Control	/	/
Red Blood Cell Folate Releasing Reagent	/	/
Cancer Antigen 72-4 (CLIA)	/	/
Neuron-specific enolase (CLIA)	/	/
CYFRA 21-1 (CLIA)	/	/
Antibody to Treponema pallidum (CLIA)	/	/
CA72-4 Calibrators	/	/
Cyfra21-1 Calibrators	/	/
Anti-TP Calibrators	/	/
NSE Calibrators	/	/
Tumor Marker Multi Control	/	/
NSE Control	/	/
Anti-TP Control	/	/

mindray

BS-2000 Modular System

Clinical Chemistry Solution



Mindray Clinical Chemistry Solution

High Throughput

2000 photometric tests/hour

Up to 600 tests/hour for ISE

Up to four modules integrated capability

Flexible scalability

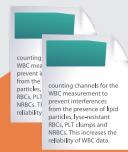
High Performance Instrument



BS-2000
Modular System



Original Calibrators
and Controls



Quality Management
System

Professional Service

Advanced Software

Results traceability

Reflex function

Flexible STAT & rerun

Real-time status monitoring

CAUTION
LIQUID PROBE COLLISION
The PLT test probe is primary
probe. Do not touch the probe
when the PLT test is running.



Reliable Results

- Advanced mechanical system
- Complete reference system
- Integral traceability system
- International traceability certificate

Reliable Results

Standardization
Laboratory

Reference
Laboratory

Dedicated Chemistry
Reagents

Dedicated Reagent System

Dedicated Reagent System

- Wide panel clinical chemistry assays
- Original calibrators and controls
- Reliable performance
- ISO standard quality

WARNING
MOVING PARTS
Do not touch when in operation.

CAUTION
AVOID FINGER COLLISION
Ensure that the door opens in primary
direction. Do not remove the cover
when in operation.

WARNING
MOVING PARTS
Do not touch when in operation.

BS-2000 Modular System

Reagent Carousel 2

1. 70 positions (40 outer and 30 inner) for R2 and R4
2. 2°C-8°C constant cooling compartment
3. Reagents can be online loaded while instrument is running

Probe R21 and Probe R22

1. 10µl-200µl, with increment of 0.5µl
2. Bubble detection, liquid level detection
3. Collision protection and auto recovery from collision

Probe R11 and Probe R12

1. 80µl-200µl, with increment of 0.5µl
2. Bubble detection, liquid level detection
3. Collision protection and auto recovery from collision

Reagent Carousel 1

1. 70 positions (40 outer and 30 inner) for R1 and R3
2. 2°C-8°C constant cooling compartment
3. Reagents can be online loaded while instrument is running

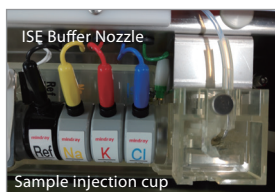
Return Lane

Reaction Carousel

1. 80µl minimum reaction volume
2. 412 glass cuvettes for permanent use
3. Direct solid heating

6-head Sample Mixer

1. Flat mixing bar with high efficiency
2. Two-step washing with pre-heated detergent and water
3. Easy replacement and maintenance



Indirect ISE

- Low sample volume, high ISE analysis throughput, and cost-effective electrodes.
- Independent buffer aspiration system – buffer syringe transfers ISE reagent to mixer through ISE buffer nozzle.

Dual-needle S

1. 1.5µl-25µL, with increment of 0.5µl
2. Clog detection, bubble detection and tracking
3. Collision protection and auto recovery from collision

System Layout

Reagent Mixers / 6-head Reagent Mixers

Efficiency
Pre-heated
Maintenance



8-stage Cuvette Wash Station

1. Cuvette washing with pre-heated detergent and water
2. Independent water blank measurement



Sample Delivery Module (SDM)

1. Patented double-layer & basket delivery design, up to 600 sample positions
2. Continuous sample loading and off loading
3. 5 types of racks

Sample Carousel

1. 140 positions for different types of sample tubes
2. 25 positions in cooling compartment for calibrators and controls
3. Flexible for STAT, rerun or other routine samples with higher priority

Individual STAT Lane

1. 32s quick response
2. One touch to initiate analysis

Sample Probe

Measurement of 0.1µL
Sensitivity for low level detection, level
control and auto recovery

Passing Lane

1. Higher priority for STAT, calibrator, control and rerun racks
2. For routine sample racks to be transferred to other analytical unit(s)

Normal Lane

Advanced Software



User-friendly Interface

- Unified platform for BS-2000 series, BS-800 series, BS-480 and future instrument
- Real-time status monitoring of analytical unit, SDM and carousels

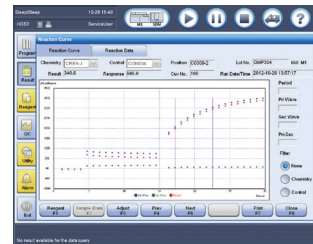


Real-time QC Status Monitoring

- Westgard Rules and Two-Control Evaluation check
- Levey-Jennings chart and Twin-Plot chart for review
- Real-time alarm and locating when QC result(s) is out of range
- Auto QC setup capability

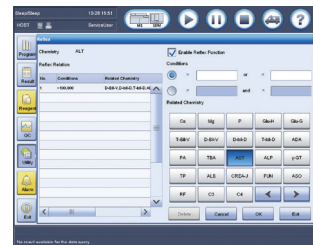
Traceable Test Results

- Reagent, calibrator and control information can be recalled from archive history
- User-friendly, intuitive software design, easy to trace results



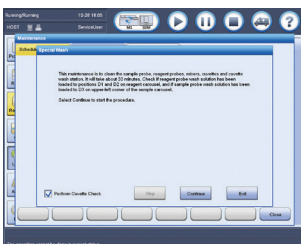
Reflex Function

- Pre-defined reflexive assays will be performed automatically when preset criteria is met
- Each assay may involve multiple reflexive criterias
- Each criteria may initiate up to a maximum of 20 relevant assays



Test Summary

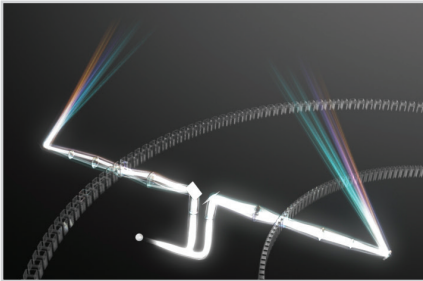
- Test summary during certain period, including calibration, QC, sample, valid tests and rerun tests
- Facilitate to computation of total test costs within a defined period
- The summary can be archived into excel files or printed for review and backup



Step-by-step Maintenance Guide

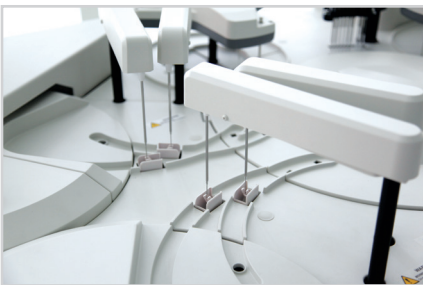
- Scheduled maintenance and maintenance guide for chemistries and ISE
- Ensure performance reliability and reduce unnecessary service calls
- Error report transferrable to service engineers for immediate troubleshooting; minimize instrument downtime

Reliable Results



Enhanced Optical System

- Dual-optical system with same light source
- Dual-lens and dual-diaphragm technology
- 80 μ L minimum reaction volume



High Precision Aspirating

- 1.5 μ L-25 μ L, with increment of 0.1 μ L for sample probe
- Non-touch dispensing for sample
- 80 μ L-200 μ L, with increment of 0.5 μ L for R11 and R12 probes
- 10 μ L-200 μ L, with increment of 0.5 μ L for R21 and R22 probes

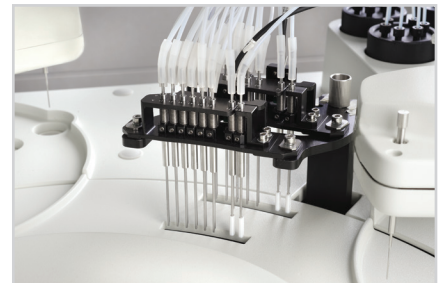
High Performance Reaction System

- Two 6-head mixing units for reagent and samples
- Direct solid heating for reaction carousel
- Glass cuvettes for permanent use



Efficient Washing System

- Interior & exterior probe washing with high pressure pre-heated water
- Programmable enhanced washing with detergent for reagent and sample probes
- 8-stage cuvette wash station, washing cuvettes with pre-heated detergent and water
- Two-step mixer washing with pre-heated detergent and water



Stable Cooling Compartment

- 2°C-8°C constant cooling compartment for reagents
- Constant cooling compartment for calibrators and controls in sample carousel



Accurate, Reliable Results

To ensure accuracy, reliability and correlation of diagnostic data, Mindray utilizes the International Standard in result reporting. To assure ease of report retrieving, Mindray establishes the Mindray Clinical Chemistry Measurement System for result traceability.



Standard reference system

- Adopt JCTLM reference system
- IFCC primary method for enzyme, ID/MS method for substrate
- NIST, IRMM reference materials



JCTLM, Joint Committee On Traceability In Laboratory Medicine

NIST, National Institute of Standards and Technology, USA

IRMM, Institute for Reference Materials and Measurements, EU

IFCC, International Federation of Clinical Chemistry and Laboratory Medicine

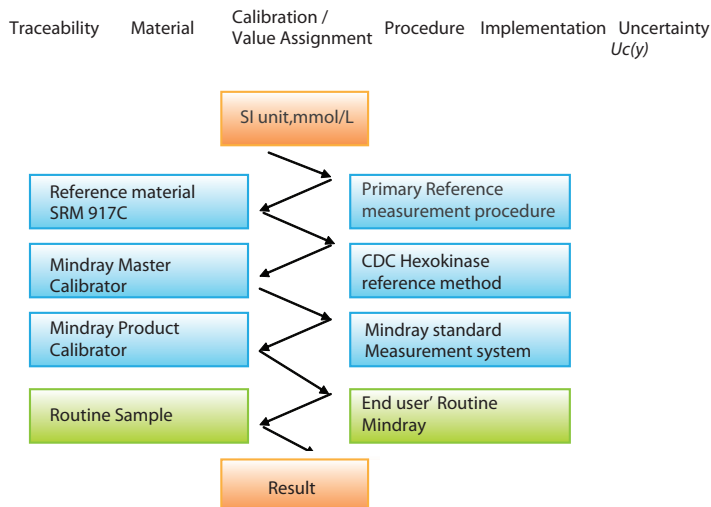
Complete traceability process

- Complete calibration hierarchy and traceability chain based on ISO standard (EN/ISO17511) from reference system to routine measurement system

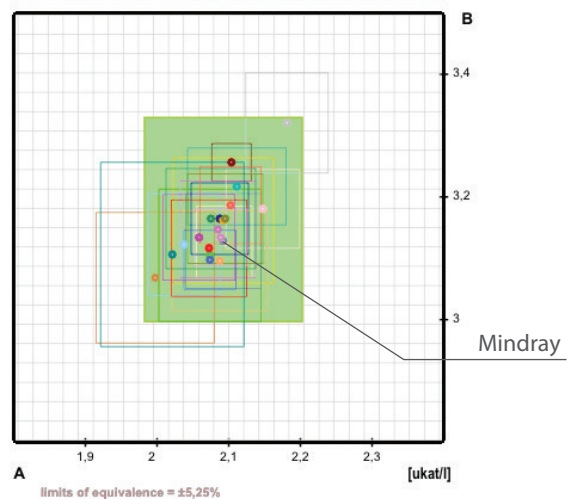
Proficiency testing for reference measurement

- Participate RELA (External quality control for reference laboratory) to verify the accuracy of the value assignment procedure.

Traceability chain of Mindray measurement system (Glu)



ALT



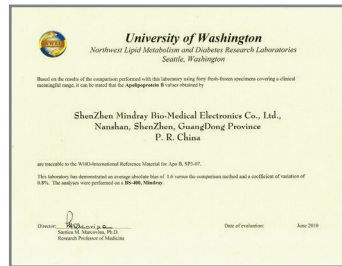
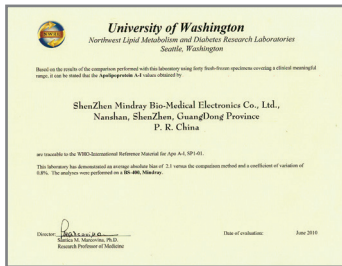
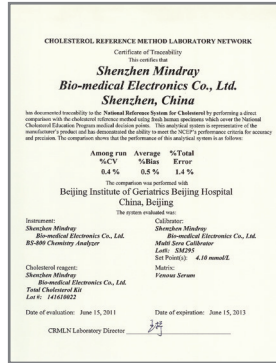
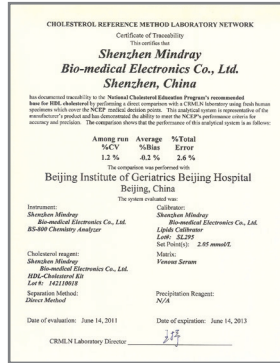
International standardization certification

- International Standardization certificates of Cholesterol and Hba1c from CRMLN and NGSP.

More information refers to website (<http://www.cdc.gov>).

CRMLN (Cholesterol Reference Method of Laboratory Network)

NGSP(National glycosylated hemoglobin standardization program)



Matched calibrators and controls

- Dedicated calibrators with traceability and specific target value
- Convenient design of multi items of calibrators and controls combined into one vial
- Long shelf life of lyophilized powder

Dedicated, high-quality reagents

- Diagnostic function test panels

Test panels such as : Hepatic panel, renal panel, pancreatic panel, lipid panel, cardiac panel, diabetic panel, rheumatic factor panel

- Reliable analysis performance

EP series standard (CLSI)-evaluate and optimize reagent system for reliable performance in precision, linearity, stability, specificity and anti-interference capability

- ISO standard manufacturing

Mindray follow straightly the ISO Certified manufacturing process to ensure every lot of reagent in production are of supreme quality



Reagent Menu

Hepatic Panel

Alanine Aminotransferase (ALT)
Aspartate Aminotransferase (AST)
Alkaline Phosphatase (ALP)
 γ -GlutamylTransferase (γ -GT)
Bilirubin Direct (Bil-D) DSA Method
Bilirubin Direct (Bil-D) VOX Method
Bilirubin Total (Bil-T) DSA Method
Bilirubin Total (Bil-T) VOX Method
Total Protein (TP)
Albumin (ALB)
Total Bile Acids (TBA)
Prealbumin (PA)
Cholinesterase (CHE)
 α -L-fucosidase (AFU)
5'-nucleotidase (5'-NT)

Renal Panel

Urea (UREA)
Creatinine (CREA) Modified Jaffé Method
Creatinine (CREA)Sarcosine Oxidase Method
Uric Acid (UA)
Carbon dioxide (CO2)
Microalbumin
 β 2-Microglobulin (β 2-MG)
Cystatin C (CysC)
Retinol binding protein(RBP)

Cardiac panel

Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Lactate Dehydrogenase (LDH)
 α -Hydroxybutyrate Dehydrogenase(α -HBDH)
High sensitive C-reactive protein (HS-CRP)
Homocysteine (HCY)
Myoglobin(MYO)
D-Dimer(D-Dimer)

Inorganic & Anemia

Iron (Fe)
Ferritin (FER)
Transferrin (TRF)
Calcium (Ca)
Magnesium (Mg)
Phosphorus (P)
Unsaturated iron binding capacity (UIBC)
Glucose-6-phosphate dehydrogenase (G6PD)

Lipid Panel

Total Cholesterol (TC)
Triglycerides (TG)
HDL-Cholesterol (HDL-C)
LDL-Cholesterol (LDL-C)
Apolipoprotein A1 (ApoA1)
Apolipoprotein B (ApoB)
Lipoprotein(a) [Lp(a)]

Immune Panel

Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Immunoglobulin E (IgE)
Complement C3 (C3)
Complement C4 (C4)

Diabetes Panel

Glucose (Glu) GOD-POD Method
Glucose (Glu) HK Method
Hemoglobin A1c (HbA1c)
Fructosamine (FUN)
 β -Hydroxybutyrate(β -HB)

Rheumatism Panel

C-reactive protein (CRP)
Rheumatoid Factor (RF)
Antistreptolysin "O"(ASO)

Pancreatitis Panel

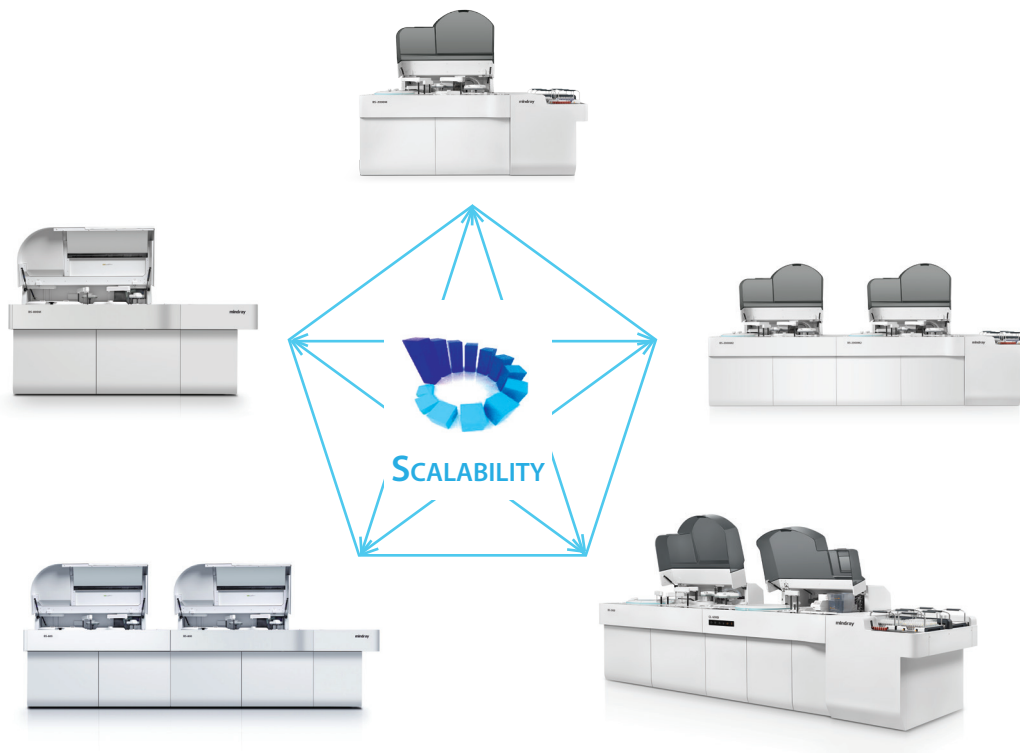
α -Amylase (α -AMY)
Lipase (LIP)

Lung Panel

Adenosine Deaminase (ADA)
Angiotensin Converting Enzyme(ACE)



Flexible Scalability



BS-2000 Modular System, the highest throughput chemistry system ever designed by Mindray, is a brand new solution package for hospitals and clinical laboratories with high sample volumes. It combines innovation and high performance into a fully integrated solution, together with the complete line of original reagents, calibrators with metrological traceability and controls. It offers customers a versatile solution with high efficiency, automation and scalability. Furthermore it will lay the foundation for further modular integration with Mindray's future products.



Technical Specifications *

System function

Fully automated, discrete, random access, STAT sample priority
Throughput: 2000 photometric tests/hour, up to 600 tests/hour for ISE
Measuring Principles: Colorimetry, Turbidimetry and Indirect ISE method
Methodology: End-point, Fix-time, Kinetic, optional ISE

Sample Handling

Sample Carousel: 140 positions, 25 cooling positions for calibrators and controls
Sample Delivery Module (SDM): Patented double-layer & basket delivery design, up to 600 sample positions
Sample Racks: 10 samples/rack
Sample Probe: Liquid level detection, clot & bubble detection, horizontal and vertical collision protection
Sample Volume: 1.5 μ l-25 μ l, with increment of 0.1 μ l
Probe Washing: Interior and exterior probe washing
Programmable enhanced washing with detergent
Carry over < 0.1%
Automatic Sample Dilution: Pre-dilution, post-dilution and auto-dilution for sample
Dilution ratio: 4~134
Barcode Reader: Integrated bar code scanner in SDM
Sample carousel barcode scanner (optional)

Reagent Handling

Reagent Carousel: 140 positions
Refrigerated compartment (2~8 $^{\circ}$ C)
Reagent Bottle: Mindray 20ml and 62ml
Barcode Reader: Bar code scanner for two reagent carousels
Reagent Probe: Liquid level detection, clot & bubble detection, horizontal and vertical collision protection
Reagent Volume: 80 μ l-200 μ l, with increment of 0.5 μ l for R11 & R12 probes
10 μ l-200 μ l, with increment of 0.5 μ l for R21 & R22 probes
Probe Washing: Automatic interior and exterior probe washing
Programmable enhanced washing with detergent
Carry over < 0.1%
Reagent Loading: Reagent bottles can be online loaded while instrument is running

Reaction System

Reaction Carousel: 412 permanent glass cuvettes with 8-stage automatic washing
Cuvette: Optical length 5mm
Reaction Volume: 80 μ l-280 μ l
Reaction Temperature: 37 $^{\circ}$ C with fluctuation of \pm 0.1 $^{\circ}$ C
Mixing Unit: Two 6-head highly polished mixing bar units for reagent mixing and sample mixing; two-step washing with pre-heated detergent and water

Optical System

Light Source: 12V/50W Halogen-tungsten lamp
Photometer: Holographic concave flat-field gratings
Wavelength: 13 wavelengths: 340nm~850nm
Absorption Range: 0~3.5A (10mm conversion)
Resolution: 0.0001Abs

ISE Module (Optional)

Indirect Method, Na⁺, K⁺, Cl⁻ tests, with 22 μ l sample volume
Throughput: up to 600 tests/hour

Operation Unit

Operation System: Window XP Professional or Windows 7 Professional (32bit)

Working Conditions

Power Supply: 110V/115V~, 60Hz; 220V-240V~, 50Hz; 220V/230V~, 60Hz
Input Power: 4500VA for each analytical unit, SDM: 800VA
Operating Temperature: 15 $^{\circ}$ C~30 $^{\circ}$ C
Relative Humidity: 35%RH~85%RH, without condensation
Water consumption: <85L/hour De-ionized water
Dimension: 1600mm(Length) \times 1050mm(Depth) \times 1300mm (Height)
for each analytical units, 710mm(Length) \times 1020mm(Depth)
 \times 1000mm(Height) for SDM
Weight: \leq 550Kg for each analytical unit, 150kg for SDM

*For single analytical unit



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

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

Certification Mark:



Scope of Certificate: See Page 2 for Overall Scope Statement.

Standard(s): ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: SH2005501

Effective Date: 2020-08-12

Expiry Date: 2023-06-30

Page 1 of 4

Date of Issue: 2020-08-20

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



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 2 of 4

Date of Issue: 2020-08-20

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



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies):

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

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 3 of 4

Date of Issue: 2020-08-20

A handwritten signature in blue ink that reads "Tina Israel".

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

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



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.