

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

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

Product: **Attachment I**

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

Conformity Assessment Route: IVDD Annex III (not includes 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.

Place, Date of Issue: Shenzhen, 2012-02-13

Signature:

Name of Authorized Signatory: Mr. Tan Chuanbin
Position Held in Company: Manager of Technical Regulation

ATTACHMENT I

Product Name	Product Model
Auto Hematology Analyzer	BC-1800
Auto Hematology Analyzer	BC-1900
Auto Hematology Analyzer	BC-2900
Auto Hematology Analyzer	BC-2600
Auto Hematology Analyzer	BC-2800
E-Z CLEANSER	M-18E
RINSE	M-18R
DILUENT	M-18D
LYSE	M-18CFL
PROBE CLEANSER	M-18P
Hematology Analyzer	BC-2100
Hematology Analyzer	BC-2300
LYSE	M-23CFL
DILUENT	M-23D
E-Z CLEANSER	M-23E
PROBE CLEANSER	M-23P
Auto Hematology Analyzer	BC-3000 Plus
Auto Hematology Analyzer	BC-3200
Auto Hematology Analyzer	BC-3000CT
Auto Hematology Analyzer	BC-3600
Auto Hematology Analyzer	BC-3300
Auto Hematology Analyzer	BC-3300CT
Auto Hematology Analyzer	BC-3600CT
DILUENT	M-30D
LYSE	M-30CFL
RINSE	M-30R
PROBE CLEANSER	\
Auto Hematology Analyzer	BC-5500
Auto Hematology Analyzer	BC-5200
LYSE	M-50LEO(I)
LYSE	M-50LEO(II)
LYSE	M-50LH
LYSE	M-50LBA
DILUENT	M-50D
CLEANSER	M-50
PROBE CLEANSER	M-50P
Auto Hematology Analyzer	BC-5100
Auto Hematology Analyzer	BC-5300
Auto Hematology Analyzer	BC-5180

Auto Hematology Analyzer	BC-5380
LYSE	M-53LEO(I)
LYSE	M-53LEO(II)
LYSE	M-53LH
DILUENT	M-53D
CLEANSER	M-53
PROBE CLEANSER	M-53P
Auto Hematology Analyzer	BC-5600
Auto Hematology Analyzer	BC-5800
LYSE	M-58LEO(I)
LYSE	M-58LEO(II)
LYSE	M-58LH
LYSE	M-58LBA
DILUENT	M-58D
PROBE CLEANSER	\
Auto Hematology Analyzer	BC-6600
Auto Hematology Analyzer	BC-6800
DILUENT	M-68DR
DILUENT	M-68DS
LYSE	M-68LD
LYSE	M-68LN
LYSE	M-68LB
LYSE	M-68LH
DYE	M-68FN
DYE	M-68FR
DYE	M-68FD
PROBE CLEANSER	\
Hematology Control	B30
Hematology Calibrator	S30
Hematology Control	B55
S50 Calibrator	\
Hematology Control	BC-3D
Hematology Control	BC-5D
Hematology Calibrator	SC-CAL PLUS
Chemistry Analyzer	BS-300
Chemistry Analyzer	BS-320
Chemistry Analyzer	BS-200
Chemistry Analyzer	BS-220
Chemistry Analyzer	BS-400
Chemistry Analyzer	BS-420
Semi-auto Chemistry Analyzer	BA-88A
Chemistry Analyzer	BS-330
Chemistry Analyzer	BS-350

Chemistry Analyzer	BS-380
Chemistry Analyzer	BS-390
Chemistry Analyzer	BS-120
Chemistry Analyzer	BS-130
Chemistry Analyzer	BS-180
Chemistry Analyzer	BS-800
Chemistry Analyzer	BS-820
Chemistry Analyzer	BS-1800
Chemistry Analyzer	BS-1800Plus
Chemistry Analyzer	BS-800M
Chemistry Analyzer	BS-820M
Chemistry Analyzer	BS-200E
Chemistry Analyzer	BS-220E
Chemistry Analyzer	BS-330E
Chemistry Analyzer	BS-350E
Microplate reader	MR-96A
Microplate washer	MW-12A
Urinalysis Reagent Strips	U-11
Urine Analyzer	UA-66
Urine Analyzer	UA-600
Urine Analyzer	UA-600T
MR Serum Standard	\
MR Urine Standard	\
MR Urine Quality Control	\
MR Buffer Solution	\
MR Detergent Solution	\
MR Na/K Check Solution	\
Detergent	CD80
α -Amylase (α -AMY) Kit (IFCC Method)	\
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(Bromocresol 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)	\
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)	\
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)	\
Lipase Kit(Enzymatic Colorimetric Assay Method)	\
Hemoglobin A1c Kit (Enzymatic Assay Method)	\
High Sensitivity C-reaction Protein Kit(Particle-enhanced Immunoturbidimetric Assay Method)	\
Rheumatism Control N	\
Rheumatism Control P	\
FUN Control P	\
CO2 Control N	\
HCY Control N	\
HCY Control P	\
HbA1C Control N	\
HbA1C Control P	\
FER Calibrator	\
Multimmun Control	\
Ferritin(FER)Kit	\
MALB Calibrator	\
MALB Control	\
Microalbumin(mALB)Kit	\
TRF Calibrator	\
TRF Control	\
Transferrin(TRF)Kit(Immunoturbidimetric Assay Method)	\
UIBC Calibrator	\
UIBC Control	\
Unsaturated Iron Binding Capacity (UIBC)Kit(Colorimetric Method)	\