

Shenzhen Mindray Bio-Medical Electronics
Co., Ltd.
Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

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

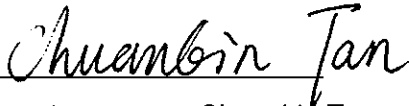
Product Category(ies): Clinical Chemistry and Hematology Analyzers, Eliza washer, Eliza reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer Analyzer, Reagents for Clinical Chemistry, Reagents for Chemiluminescence Immunoassay Analyzer, Urinalysis reagent strips.

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, **2014-12-24**



Signatory name: Chuanbin Tan

signatory title: Technical Regulation Manager

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.



**TỔNG GIÁM ĐỐC
LÊ THANH NGHĨ**

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 Keji 12th Road South, Hi-tech Industrial Park,
 Shenzhen 518057, P. R. China
 Tel: +86 755 26582888
 Fax: +86 755 26582500

ATTACHMENT I

| Product Name | Product Model | Accessories |
|--------------------------|-------------------------------|---|
| Auto 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 BC-5200 | M-50D DILUENT 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 |

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

| | | |
|--------------------------|---|--|
| | | 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 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 |

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

| | | |
|--------------------------|--------------------------|---|
| 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 |
| 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 |
| 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 | M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER BC-5D Hematology control SC-CAL PLUS Hematology Calibrator |
| Urine Analyzer | UA-66、UA-600、 UA-600T | Urinalysis reagent strips |
| 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 |

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

| | | |
|--------------------|---------------------------------|--|
| | | Tri-Level Quality Control Kit |
| Chemistry Analyzer | BS-400、BS-420、 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 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 |

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

| | | |
|------------------------------|---------------------------------|--|
| | | 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 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、BS-190 | 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 |

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

| | | |
|--------------------|---|---|
| | | <p>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</p> |
| Chemistry Analyzer | BS-200E/BS-220E BS-330E/BS-350E | <p>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</p> |
| Microplate reader | MR-96A | / |
| Microplate washer | MW-12A | / |
| Chemistry Analyzer | BS-800、BS-820、 BS-800M 、 BS-820M 、 BS-1800、BS-1800 plus | <p>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)</p> |
| Chemistry Analyzer | BS-2000 、 BS-2000M 、 BS-2200 、 BS-2200M | <p>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</p> |

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Keji 12th Road South, Hi-tech Industrial Park,
Shenzhen 518057, P. R. China

Tel: +86 755 26582888

Fax: +86 755 26582500

| | | |
|---|----------------------|---|
| | | 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) |
| Chemiluminescence Immunoassay Analyzer | CL-2000i CL-2200i | External air pump Water supply module |
| 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) | / | / |