

“Echipamed-Plus” SRL  
str. Valea Trandafirilor, 24B, of. 2-7  
MD-2001, Chisinau, Moldova  
+373 22 234-349

October 25, 2022

**LETTER OF AUTHORIZATION**

To whom it may concern,

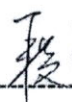
We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, (“**Mindray**”) manufacturer of **biochemical, imunological and coagulation analyzers, reagents and consumables** (“**Product(s)**”), hereby certify that “**Echipamed-Plus**” SRL, with business office at str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova (“**You**”) is our official distributor and local representative for registration, sales and service of the **Product(s)** in **Republic of Moldova** (“**Territory**”).

As the manufacturer, Mindray guarantees the **Product(s)** against defects in materials and workmanship, and provide services based on the standard terms and conditions of Mindray’s warranty policy.

This authorization of distribution rights is valid from the date of issuance to **December 31, 2023**. Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the **Product(s)**, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,

  
-----  
Duan Liang

General Manager of Sales and Marketing Division, CIS I Region  
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**





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 Immunossay 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











# 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.



# 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:** Chemistry Analyzer  
**Model:** BS-230  
**Consumables:** Reaction cuvette  
Mindray reagent bottles  
CD-80 DETERGENT  
**Optional Module:** ISE unit  
bar code reader(optional)

**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.**

**Standards Applied:**

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

**Start of CE-Marking:** 2016-03-29

**Place, Date of Issue:** Shenzhen, 2016.3.29

**Signature:** \_\_\_\_\_  
[Handwritten signature]

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



# 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:** Chemistry Analyzer  
**Model:** BS-240  
**Consumables:** Reaction cuvette  
Mindray reagent bottles  
CD-80 DETERGENT  
**Optional Module:** ISE unit  
bar code reader(optional)

**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.**

**Standards Applied:**

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

**Start of CE-Marking:** 2016-03-29

**Place, Date of Issue:** Shenzhen, 2016.3.29

**Signature:** \_\_\_\_\_  


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



## Applied Standards List

**Product:**            **BS-230/BS-240 Chemistry Analyzer**

**Applied Standards:**

EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer ( labelling ) Part 3: In vitro diagnostic instruments for professional use
ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006	Medical device software – Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices