CA-GJLA202401260006

mindray

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

**Date: 26.01.2024**

# LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, (**"Mindray"**) manufacturer of **biochemical, immunological 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, 2024.** 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,

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.

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Duan Liang
General Manager of Sales and Marketing Division, Central Asia Region
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 26582888
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Digitally signed by Iurchevici Valeriu
Date: 2024.04.22 16:16:44 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA, MUN. CHIȘINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "ECHIPAMED-PLUS" IDNO 1003600077677

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

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

TÜV SÜD
Product Service

# Certificate

**No. Q5 044751 0164 Rev. 05**

**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
tuvsud.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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 05

**Report No.:** SH2305501

**Valid from:** 2023-09-01
**Valid until:** 2026-08-31

**Date,** 2023-06-19

Christoph Dicks
Head of Certification/Notified Body

"TECHIPAMED-PLUS" IDNO 1003600077677


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## No. Q5 044751 0164 Rev. 05

**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

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)

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

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)

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Product Service

# Certificate

**No. Q5 044751 0164 Rev. 05**

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, Endoscope Light Source and accessories, 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, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer , Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer.



TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

# 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:** .....

**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.**

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**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 ( labeling ) 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 |