

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

**Date: 07.02.2025**

**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, 2025**. 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,


Gao Xiufu  
Regional Sales & Marketing Manager, IVD Sales & Marketing Department, Central Asia  
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.







TUV SUD  
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERTIFICAT



# CERTIFICATE

No. QS5 044751 0140 Rev. 05

**Overall Scope Statement:**

Design and Development, Production and Distribution of 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, 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 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, 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, Wireless Module, Wireless Device

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Page 2 of 4  
Date of Issue: 2023-05-25

( Renee Walker )  
Director, US Certification Body, MHS

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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:**



**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](http://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

*C. Dicks*

Christoph Dicks  
 Head of Certification/Notified Body







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)



ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



# 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.





Declaration of Conformity V1.0

## Declaration of Conformity



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

**Manufacturer SRN:** CN-MF-000014156

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

**Product:** Chemistry Analyzer

**Model:** BS-230/BS-240/BS-270/BS-280/ES 300

**Basic UDI-DI:** 69449040SHYQ-BA24\*\*\*\*\*ML

**Intended Purpose:** The system is an automated chemistry analyzer for in vitro diagnostic use in clinical laboratories and designed for in vitro quantitative determination of clinical chemistries in serum, plasma, urine or cerebrospinal fluid samples (sample type is chemistry dependent).

**Classification:** Class A (According to Rule 5 of IVDR annex VIII)

**Conformity Assessment Route:** Annex II and III of IVDR

**GMDN code:** 56676

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT and OF THE COUNCIL. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: /

Notified Body No. : /

Identification of the Certificate: /

Start of CE-Marking: 2022.4.25

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Manager of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

**Place, Date of Issue:**

Shenzhen, 2022.4.25

**Signature:**



**Name of Authorized Signatory:**

Mr. Wang Xinbing

**Position Held in Company:**

Deputy Director, Technical Regulation Department



## Applied Standards List

**Product:** Chemistry Analyzer  
**Model:** BS-230/BS-240/BS-270/BS-280/ES 300

**Standards Applied:**

EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
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 18113-3:2009)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	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
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

EN 61010-2-010:2020	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 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
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



Declaration of Conformity –V1.0

# Declaration of Conformity

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

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

**Product:** Chemistry Analyzer

**Model:** BS-230/BS-240/BS-270/BS-280/ES 300

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU, amended by Directive (EU) 2015/863. All supporting documentations are retained under the premises of the manufacturer.

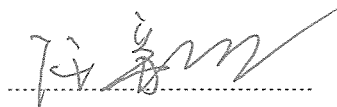
**Standards Applied:**

EN IEC 63000: 2018 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

**Start of CE-Marking:** 2022.4.25

**Place, Date of Issue:** Shenzhen. 2022.4.25

**Signature:**



**Name of Authorized Signatory:** Mr.WangXinBing

**Position Held in Company:** Deputy Director, Technical Regulation Department