

"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,

-----  
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  
Fax: +86 755 26582680  
Website: www.mindray.com





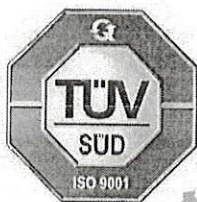
# CERTIFICATE

No. QS5 044751 0140 Rev. 05

**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.:

SH2305501

Effective Date:

2023-07-01

Expiry Date:

2026-06-30

Page 1 of 4

Date of Issue: 2023-05-25

( Renee Walker )  
Director, US Certification Body, MHS

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • [www.tuv-sud.com](http://www.tuv-sud.com)







America

# 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

Page 2 of 4

Date of Issue: 2023-05-25

( Renee Walker )  
Director, US Certification Body, MHS

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • [www.tuvsud.com](http://www.tuvsud.com)

TUV®







# CERTIFICATE

No. QS5 044751 0140 Rev. 05

**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

**Facility Scopes:**

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

Page 3 of 4

Date of Issue: 2023-05-25

( Renee Walker )  
 Director, US Certification Body, MHS

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • [www.tuvsud.com](http://www.tuvsud.com)





**No. QS5 044751 0140 Rev. 05**

**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 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

( Renee Walker )  
Director, US Certification Body, MHS





DAkkS

Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00

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

Christoph Dicks  
Head of Certification/Notified Body





# 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)



# 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:** Chemiluminescence Immunoassay Analyzer

**Model:** CL-900i、CL-920i、CL-960i、CL-980i

**Basic UDI-DI:** 69449040MY YQ-BM50\*\*\*\*\*BZ

**Intended Purpose:** The instrument is an automated Analyzer for immunological  
analysis. It is designed for determination of analytes in serum,  
plasma and other human body fluids.

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

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

**GMDN code:** 56701

**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. :** /

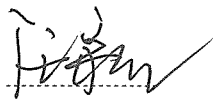
**Identification of the Certificate:** /

**Start of CE-Marking:** 2018.10.17

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

**Place, Date of Issue:** Shenzhen, 2022.5.13

**Signature:**



**Name of Authorized Signatory:** Mr. Wang Xinbing

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



## Applied Standards List

**Product:** Chemiluminescence Immunoassay Analyzer

**Model:** CL-900i、CL-920i、CL-960i、CL-980i

### 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 –V2.0

# 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:** Chemiluminescence Immunoassay Analyzer

**Model:** CL-900i、CL-920i、CL-960i、CL-980i

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 2015/863/EU. All supporting documentations are retained under the premises of the manufacturer.

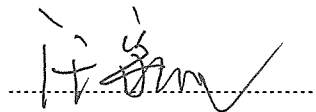
**Standards Applied:**

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:** 2018.10.17

**Place, Date of Issue:** Shenzhen. 2022.5.13

**Signature:**



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

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