

"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.

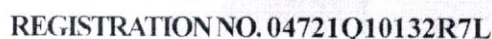
Best regards,

  
\_\_\_\_\_  
Duan Liang

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







**This is to certify that the quality management system of**

**ShenZhenMindray Bio-Medical Electronics Co., Ltd.**

Registered Address: Floor 1st~Floor 4th, Mindray Building, Keji 12th Road South, High-Tech Industrial Park,  
Nanshan, Shenzhen, P.R.China

Manufacturing Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P.R.China; 1203 Nanhuan Avenue, Guangming District, Shenzhen, P. R. China

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

**The certificate is valid for the following scope:**

The Design, Development, Production and Service of Endoscope light source ,Diagnostic Ultrasound System , Endoscope Camera System, Microplate washer , UltraSync, patient monitor, Center Monitoring System, Telemetry Monitoring System, Vital Signs Monitor, Pulse Oximeter, Vital Signs Monitor & Patient Monitors, Disposable SpO2 Sensor, SpO2 Sensor, ECG Cable, NIBP Cuff, Temperature Probe, Holter, Wearable ECG Monitor, Analysis system, Defibrillator/Monitor, Electrocardiograph, Anesthesia Machine, Ventilator, Ultrasound Diagnostic System, Digital Ultrasonic Diagnostic Imaging System, Ultrasound Imaging Administration System, Digital Radiography System, Mobile radiography system, Mobile Stand, Radiography Imaging Information System, retropad detector and its imaging system, Auto Hematology Analyzer, Urine Analyzer, Auto Silde Maker&Statiner, Flow Cytometer, Automatic Glycohemoglobin Analyzer, Specific Protein Analyzer, Sample Processing System, Chemistry Analyzer, Semi-auto Chemistry Analyzer, Microplate reader, Chemiluminescence Immunoassay Analyzer, CPR sensor, VS-900 Neo Vital Signs Monitor, Automated External Defibrillator, Ultrasonic Transducer, Automated Digital Cell Morphology Analyzer and Vitro Diagnostic Reagent (within the scope of manufacturing license)

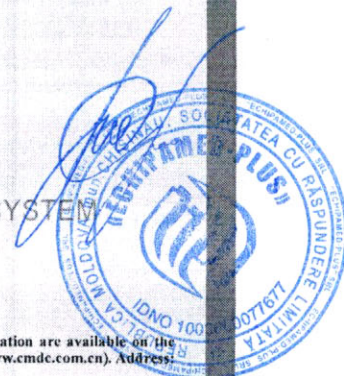
**Date of issue: April 15,2021**

**Date of expiry: April 05,2024**

**Date of change: May 31,2022**

**General Manager:**

**BEIJING HUA GUANG CERTIFICATION  
OF MEDICAL DEVICES CO., LTD.**



Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No.1188, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993





Product Service

# Certificate

No. Q5 044751 0164 Rev. 02

**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). See also notes overleaf.

**Report No.:** SH2005501

**Valid from:** 2020-09-01  
**Valid until:** 2023-08-31

**Date,** 2020-07-24

Christoph Dicks  
Head of Certification/Notified Body



**No. Q5 044751 0164 Rev. 02**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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

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







DAkkS

Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00

Product Service

# 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



**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-1000i, CL-1200i

**Basic UDI-DI:** 69449040MYQ-BM20\*\*\*\*\*A8

**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:** /

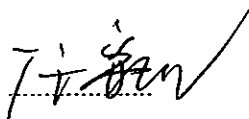
**Start of CE-Marking:** 2016.11.22

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, 2022.4.26

**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-1000i、CL-1200i

**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

**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-1000i、CL-1200i

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:** 2016.7.22

**Place, Date of Issue:** Shenzhen. 2022.4.26

**Signature:** 

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

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