mindray

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

Date: 03.12.2021

# LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, (**"Mindray"**) manufacturer of **CL-900i, CL-1000i, CL-1200i, BS-230, BS-240pro, BS-430, BS-800, corresponding reagents and consumables ("Products")**, hereby certify that we authorize **"Echipamed-Plus" SRL,** with business office at **str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova ("You")** as the exclusive distributor and local representative for sales and service of the Products in **Republic of Moldova ("Territory").**

As the manufacturer, Mindray guarantees the Products 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, 2022.** 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 Products, 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
**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 81888998
Fax: +86 755 26582680
Website: www.mindray.com

REPUBLICA MOLDOVA MUNICIPIUL CHISINAU, SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677

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

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**


**Date of Issue:** 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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

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**


**Date of Issue:** 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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

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


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

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

A4 / 07.17

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D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## No. Q5 044751 0164 Rev. 02

**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

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


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

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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.


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Declaration of Conformity V 1.0

# Declaration of Conformity CE

| | |
|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80<br>20537 Hamburg, Germany |

**Product:** **Chemiluminescence Immunoassay Analyzer**

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

**Classification:** The device not in IVDD annex II and not for self testing/performance evaluation

**Conformity Assessment Route:** IVDD Annex III (excluding Section 6)

**We herewith declare under our sole responsibility 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:** 2018-10-17

**Place, Date of Issue:** Shenzhen, 2018-10-17

**Signature:** .....

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

**Position Held in Company:** Manager of Technical Regulation

Declaration of Conformity V 1.0

# Applied Standards List

| Product | Chemiluminescence Immunoassay Analyzer<br>CL-900i, CL-920i, CL-960i, CL-980i |
|---|---|

**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 |
| 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 13612:2002 | Performance evaluation of in vitro diagnostic medical devices |
| EN ISO 14971:2012 | Medical devices - Application of risk management to medical devices |
| EN 61010-1:2010 | Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement |
| IEC 61010-2-101:2015 | Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment |
| EN 61010-2-081: 2015 | 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 61010-2-010:2014 | Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010:Particular requirements for laboratory equipment for heating of materials |
| EN 61326-1:2013 | Electrical equipment for measurement control and laboratory use-EMC requirements-Part1: General requirement |
| EN 61326-2-6:2013 | Electrical equipment for measurement control and laboratory use-EMC requirements-Part2-6: Particular requirement-In vitro diagnostic (IVD) medical equipment |
| EN 62304:2015 | Medical device software - Software life-cycle processes |
| IEC 62366-1:2015 | Medical devices — Application of usability engineering to medical devices |