Digitally signed by Iurchevici Valeriu
Date: 2023.07.03 13:29:50 EEST
Reason: MoldSign Signature
Location: Moldova
CIS-GJLA202210260016

mindray

"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.

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

REGISTRATION NO. 04721Q10132R7L

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

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.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

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.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

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

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

TÜV SÜD
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.

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

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Declaration of Conformity V1.0

Declaration of Conformity

CE

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:	69449040MYYQ-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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

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 –V2.0

Declaration of Conformity CE

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