

"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.

**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
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Website: www.mindray.com



No. QS5 044751 0140 Rev. 05

**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



See Page 2 for Overall Scope Statement.

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.

SH2305501

2023-07-01

2026-06-30

Date of Issue: 2023-05-25

(Renee Walker)
Director, US Certification Body, MHS

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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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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

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Date of Issue: 2023-05-25

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America

CERTIFICATE

No. QS5 044751 0140 Rev. 05

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 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

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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

Report No.: SH2305501

Valid from: 2023-09-01
Valid until: 2026-08-31

Date, 2023-06-19

Christoph Dicks
Head of Certification/Notified Body





DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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)



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.

