

"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.**





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

Page 1 of 4

Date of Issue: 2020-08-20

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

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • [www.tuvsud.com](http://www.tuvsud.com)





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

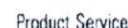
Page 2 of 4

Date of Issue: 2020-08-20

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

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • [www.tuvsud.com](http://www.tuvsud.com)







**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



To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:

We herewith declare that the products listed in Attachment I and Attachment II meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices.

**Product Category I :** Reagents for Chemiluminescence Immunoassay Analyzer

**Products:** Attachment I

**Classification:** List B in IVDD annex II

**Conformity Assessment Route:** Annex IV.3

**Notified Body:** TÜV SÜD Product Service GmbH,  
Ridlerstraße 65, 80339 München, Germany.

**Notified Body NO:** 0123

**Product Category II:** Reagents for Chemiluminescence Immunoassay Analyzer

**Products:** Attachment II

**Classification:** List A in IVDD annex II

**Conformity Assessment Route:** Annex IV.3 and IV.4

**Notified Body:** TÜV SÜD Product Service GmbH,  
Ridlerstraße 65, 80339 München, Germany.

**Notified Body NO:** 0123

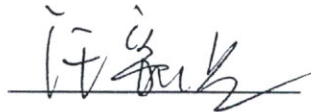


**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

We hereby certify that the forgoing is a true and accurate statement.

Place, Date Of Issue : Shenzhen, 2017-11-1



**Signatory name:** Xinbing Wang

**Signatory title:** Technical Regulation Manager

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

### ATTACHMENT I

<b>Mindray Product list</b>
Total Prostate Specific Antigen (CLIA)
Total PSA Calibrators
Free Prostate Specific Antigen (CLIA)
Free PSA Calibrators
Tumor Marker Multi Control

### ATTACHMENT II

<b>Mindray Product list</b>
Hepatitis B Surface Antigen (CLIA)
Antibody to Hepatitis B Surface Antigen (CLIA)
Hepatitis B e Antigen (CLIA)
Antibody to Hepatitis B e Antigen (CLIA)
Antibody to Hepatitis B Core Antigen (CLIA)
Antigen and Antibodies to Human Immunodeficiency Virus (CLIA)
HBsAg Calibrators
Anti-HBs Calibrators
HBeAg Calibrators
Anti-HBe Calibrators
Anti-HBc Calibrators
HIV Calibrators
HBsAg Positive Control





HBsAg Negative Control
Anti-HBs Positive Control
Anti-HBs Negative Control
HBeAg Positive Control
HBeAg Negative Control
Anti-HBe Positive Control
Anti-HBe Negative Control
Anti-HBc Positive Control
Anti-HBc Negative Control
HIV Ag/Ab Positive Control
HIV Ag/Ab Negative Control



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
518057, P. R. China  
Tel: +86 755 26582888  
Fax: +86 755 26582500



## DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:

We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices.

**Product Category:** Auto Hematology Analyzer and the reagents for Auto Hematology Analyzer, Semi-auto Chemistry Analyzer, Microplate reader , Microplate washer, Chemiluminescence Immunoassay Analyzer and the reagents for Chemiluminescence Immunoassay Analyzer

**Products:** Attachment I

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

**Conformity Assessment Route:** Annex III (not includes Section 6)

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, Germany

We hereby certify that the forgoing is a true and accurate statement.

Place, Date Of Issue : Shenzhen, 2017-11-1

**Signatory name:** Xinbing Wang

**Signatory title:** Technical Regulation Manager

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**





Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

## **ATTACHMENT I**

### **Equipments**

<b>Product Name</b>	<b>Model</b>
Auto Hematology Analyzer	BC-2800
Auto Hematology Analyzer	BC-2800Vet
Auto Hematology Analyzer	BC-3000Plus
Auto Hematology Analyzer	BC-3200
Auto Hematology Analyzer	BC-3600
Auto Hematology Analyzer	BC-20s
Auto Hematology Analyzer	BC-30s
Semi-auto Chemistry Analyzer	BA-88A
Microplate reader	MR-96A
Microplate washer	MW-12A
Chemiluminescence Immunoassay Analyzer	CL-1000i

### **Reagents, Calibrators, Controls and Consumables for Auto Hematology Analyzer**

<b>Product Name</b>	<b>Model</b>
M-30D DILUENT	M-30D
M-30CFL LYSE	M-30CFL
M-30R RINSE	M-30R
M-30E E-Z CLEANSER	M-30E
M-30P PROBE CLEANSER	M-30P
PROBE CLEANSER	\
Hematology Control	B30
Calibrator	S30
Hematology Control	BC-3D
Hematology Calibrator	SC-CAL Plus

### **Reagents for Chemiluminescence Immunoassay Analyzer**

Free Triiodothyronine (CLIA)
Free Thyroxine (CLIA)
Total Triiodothyronine (CLIA)



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

Total Thyroxine (CLIA)
Thyroid-Stimulating Hormone (CLIA)
Thyroglobulin (CLIA)
Antibody to thyroglobulin (CLIA)
Antibody to thyroid peroxidase (CLIA)
Cancer Antigen 125 (CLIA)
Carbohydrate Antigen 19-9 (CLIA)
Carcinoembryonic Antigen (CLIA)
Alpha-fetoprotein (CLIA)
Cancer Antigen 15-3 (CLIA)
Cancer Antigen 72-4 (CLIA)
CYFRA 21-1 (CLIA)
Neuron-specific enolase (CLIA)
Total $\beta$ Human Chorionic Gonadotropin (CLIA)
Luteinizing Hormone (CLIA)
Follicle Stimulating Hormone (CLIA)
Prolactin (CLIA)
Estriol (CLIA)
Progesterone (CLIA)
Testosterone (CLIA)
Estradiol (CLIA)
Insulin (CLIA)





Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

C-peptide (CLIA)
Dehydroepiandrosterone sulfate (CLIA)
Cortisol (CLIA)
Adrenocorticotrophic hormone (CLIA)
Troponin I (CLIA)
Myoglobin (CLIA)
Creatine kinase MB (CLIA)
B-type natriuretic peptide (CLIA)
Parathyroid hormone (CLIA)
Calcitonin (CLIA)
25-OH-Vitamin D Total (CLIA)
Ferritin (CLIA)
Vitamin B12 (CLIA)
Folate (CLIA)
Red Blood Cell Folate Releasing Reagent
Antibody to Treponema pallidum (CLIA)

#### **Calibrators for Chemiluminescence Immunoassay Analyzer**

Free T3 Calibrators
Free T4 Calibrators
Total T3 Calibrators
Total T4 Calibrators



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China  
 Tel: +86 755 26582888  
 Fax: +86 755 26582500

TSH Calibrators
Thyroglobulin Calibrators
Anti-Tg Calibrators
Anti-TPO Calibrators
CA125 Calibrators
CA19-9 Calibrators
CEA Calibrators
AFP Calibrators
CA15-3 Calibrators
CA72-4 Calibrators
CYFRA21-1 Calibrators
NSE Calibrators
Total $\beta$ HCG Calibrators
LH Calibrators
FSH Calibrators
Prolactin Calibrators
Estriol Calibrators
Progesterone Calibrators
Testosterone Calibrators
Estradiol Calibrators
Insulin Calibrators
C-peptide Calibrators
DHEA-S Calibrators
Cortisol Calibrators
ACTH Calibrators
Troponin I Calibrators
MYO Calibrators
CK-MB Calibrators
BNP Calibrators
PTH Calibrators
Calcitonin Calibrators
25-OH-Vitamin D Total Calibrators
Ferritin Calibrators
Vitamin B12 Calibrators
Folate Calibrators
Anti-TP Calibrators





Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
518057, P. R. China  
Tel: +86 755 26582888  
Fax: +86 755 26582500

**Controls for Chemiluminescence Immunoassay Analyzer**

Thyroid Function Multi Control
Reproductive Multi Control
Anti-thyroid Antibodies Control
Cardiac Marker Multi Control
Immunoassay Multi Control
ACTH Control
Metabolic Multi Control
NSE control
Anti-TP Control

**Consumables for Chemiluminescence Immunoassay Analyzer**



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
518057, P. R. China  
Tel: +86 755 26582888  
Fax: +86 755 26582500

Substrate Solution
Wash Buffer
Detergent CD80
Sample Diluent
Reaction Cuvette

