CIS-AL-L1373-66603664

Digitally signed by Iurchevici Valeriu
Date: 2021.12.23 17:40:30 EET
Reason: MoldSign Signature
Location: Moldova

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

«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

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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Akkreditierungsstelle
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.

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TÜV®

DECLARATION OF CONFORMITY CE 0123

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,
Ridlerstraβe 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,
Ridlerstraβe 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

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

ATTACHMENT II

Mindray Product list
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 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

CE

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 12th Road South, Hi-tech Industrial Park, Shenzhen
518057, P. R. China
Tel: +86 755 26582888
Fax: +86 755 26582500

ATTACHMENT I

Equipments

Product Name	Model
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

Product Name	Model
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.
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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 β Human Chorionic Gonadotropin (CLIA)
Luteinizing Hormone (CLIA)
Follicle Stimulating Hormone (CLIA)
Prolactin (CLIA)
Estriol (CLIA)
Progesterone (CLIA)
Testosterone (CLIA)
Estradiol (CLIA)
Insulin (CLIA)

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C-peptide (CLIA)
Dehyroepiandrosterone sulfate (CLIA)
Cortisol (CLIA)
Adrenocorticotropic 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

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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 β 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.
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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 12th 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

Zhejiang SKG Medical Technology Co., Ltd

Add: No.39, Anye Road,Gaoqiao Street, Huangyan, Taizhou,Zhejiang,China,318020

Tel: 0086-576-84031666 Fax: 0086-576-84036668 Http://www.skgmed.com

CE Declaration of Conformity

Manufacturer: Zhejiang SKG Medical Technology Co.,Ltd.

NO.39 Anye Road, Gaoqiao Street, Huangyan 318020 Taizhou, Zhejiang

PEOLPLE'S REPUBLIC OF CHINA

European

Representative: Shanghai International Holding corp.GmbH(Europe)

Eiffestrabe 80 20537 Hamburg GERMANY

Product Name: Sample Cup

Model Number: BS-200, 700

Classification (IVDD): Other

Conformity Assessment Route: IVDD Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied:

ISO13485:2003, ISO11135-1:2007, ISO14971:2007, ISO 15223-1-2012

Notified Body: TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65·80339

München Germany

Identification number: Not applicable

(EC) Certificate(s): Not applicable

Expire date of the Certificate: Not applicable

Start of CE Marking: Not yet

Place, Date of Issue: HuangYan 2021-12-17

Signature:

Name: Sujian

Position: General Manager

ZHEJIANG SKG MEDICAL TECHNOLOGY CO.,LTD. 浙江双康医疗科技有限公司

MECHIPAMED-PLUS