CIS-AL-LI373-66602101

mindray

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

January 27th, 2021

LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, **("Mindray")** manufacturer of **BS-120, BS-200, BS-240, CL-900i, CL-1000i, CL-1200i, 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, 2021.** 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
Sales 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 81888
Fax: +86 755 26582
Website: www.mindray.com

Digitally signed by Iurchevici Valeriu
Date: 2021.11.12 18:49:47 EET
Reason: MoldSign Signature
Location: Moldova

SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677 REPUBLICA MOLDOVA MUN. CHISINAU

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

SCC Accredited CB-MS
OCSM Accrédité CCN

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:

TÜV SÜD ISO 9001

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

TÜV®

Declaration of Conformity

CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Chemistry Analyzer**
Model:	**BS-200**
Internal code:	**BA20**
Consumables:	Reaction cuvette Mindray reagent bottles
Optional Module:	**ISE Module** **Bar Code Module**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation
Conformity Assessment Route:	IVDD Annex III (not includes Section 6)

We herewith declare 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: 2005-12-15

Place, Date of Issue: Shenzhen, 2010-11-03

Signature: .....

Name of Authorized Signatory: Mr. Yang long

Position Held in Company: Management Representative

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

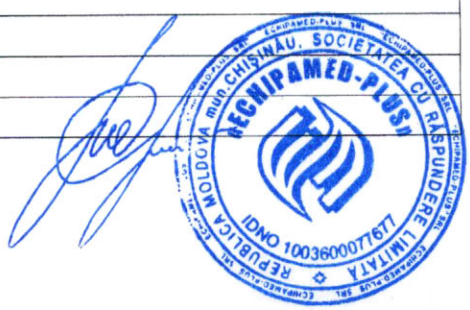
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

ATTACHMENT I

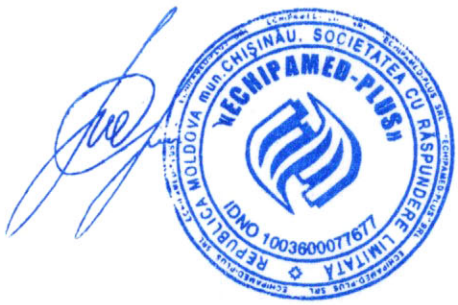
Mindray Product list
Total Prostate Specific Antigen (CLIA)
Total PSA Calibrators
Free Prostate Specific Antigen (CLIA)
Free PSA Calibrators
Tumor Marker Multi Control

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.
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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.
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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)

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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

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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

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Substrate Solution
Wash Buffer
Detergent CD80
Sample Diluent
Reaction Cuvette

Declaration of Conformity CE

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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

Product: DETERGENT C

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

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

We herewith declare 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: 2018-4-17

Place, Date of Issue: Shenzhen, 2018-4-17

Signature:

Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Manager of Technical Regulation

REPUBLICA MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS»