

"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 S18057, P.R. China Tel: +86 755 81888998 Fax: +86 755 26582680 Website: www.mindray.com









## 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







## CERTIFICATE

No. QS6 044751 0135 Rev. 01

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 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA,

MHLW / PMDA. See attached for listing of specific

regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**DUNS No:** 

65-467-1304

**Effective Date:** 

2019-08-26

**Expiry Date:** 

2021-10-23

Page 1 of 4

Date of Issue: 2019-11-25

Claim Phodean

( Dawn M. Tibodeau ) Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tw/stides





## 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-240

Consumables:

Reaction cuvette

Mindray reagent bottles

**CD-80 DETERGENT** 

**Optional Module:** 

ISE unit

bar code reader(optional)

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: 2016-03-29

Place, Date of Issue:

Shenzhen, wib.3.29

Signature:

Name of Authorized Signatory:

Mr. Tan Chuanbin

Position Held in Company:

Manager of Technical Regulation