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 [illegible]
Fax: +86 755 [illegible]
Website: www.[illegible]

Digitally signed by Iurchevici Valeriu
Date: 2021.07.07 18:23:46 EEST
Reason: MoldSign Signature
Location: Moldova

SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677 REPUBLICA MOLDOVA mun. CHIŞINĂU

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

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**

Date of Issue: 2019-11-25

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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:	Chemiluminescence Immunoassay Analyzer
Model:	CL-1000i
Consumables:	Reaction cuvettes. waste container
Optional Module:	Built-in sample bar code reader Built-in reagent bar code reader
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: 2015-09-30

Place, Date of Issue: Shenzhen, 2015-09-30

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager of Technical Regulation

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: Chemiluminescence Immunoassay Analyzer
Model: CL-1200i
Consumables: Reaction cuvettes.
waste container
Optional Module: Built-in sample bar code reader
Built-in reagent bar code reader
Hand-held bar code reader

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: 2015-09-30
Place, Date of Issue: Shenzhen, 2015-09-30

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin
Position Held in Company: Manager of Technical Regulation

Applied Standards List

Product: **Chemiluminescence Immunoassay Analyzer**
CL-1000i /CL-1200i

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices —Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labeling) Part 3: In vitro diagnostic instruments for professional use
ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081: 2002 +A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006	Medical device software – Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices