

October 21<sup>st</sup>, 2020

**AUTHORIZATION LETTER**

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd. ("Mindray")**, who are official manufacturer of Chemistry Analyzer **BS-200** and its **consumables, reagents and accessories("Products")**, located at Mindray Building, Keji 12<sup>th</sup> Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA, do hereby authorize:

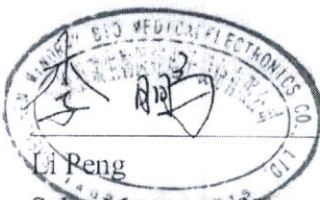
**"Echipamed-Plus" SRL**  
**str. Valea Trandafirilor, 24B, of. 80**  
**MD-2001, Chisinau**  
**Republic of Moldova**

as the **exclusive company** to submit a bid, subsequently negotiate and sign the Contract against Tender nr. **ocds-b3wdp1-MD-1601967044236(21029076)** dated on **27.10.2020** organized by **IMSP Spitalul de Stat** for the Mindray Products in **Moldova**.

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.

The present authorization is valid from the date of issuance up to **December 31<sup>st</sup>, 2020**.

Yours faithfully,



Sales Manager of International Sales and Marketing System, CIS  
**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

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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)





# Declaration of Conformity



**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

