

# 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:** Auto Hematology Analyzer  
**Model:** BC-3600

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

M-30R RINSE

PROBE CLEANSER

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

**Conformity Assessment Route:** IVDD Annex III(excluding 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:** 2011-01-14

**Place, Date of Issue:** Shenzhen, 2011-01-14

**Signature:**

**Name of Authorized Signatory:** Mr. Yang Long

**Position Held in Company:** Management Representative



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**

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Date of Issue: 2019-11-25

( Dawn M. Tibodeau )  
Manager, Certification Body MHS

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# CERTIFICATE

No. QS6 044751 0135 Rev. 01

## Regulatory Requirements: Audit/Certification Criteria

### Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

### Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

### Canada

- Medical Device Regulations SOR/98-282, Part 1

### United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

### Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

## Overall Scope Statement:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls; 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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# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**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

**Facility Scopes:**

**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

Design and Development, Production and Distribution of  
Medical Electronic Equipment (including Patient Monitor and  
Accessories (NIBP House, NIBP Cuff, Sensor Cables including  
SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG  
Cables and Leadsets, Temperature Probe, Probe Cover),  
Vital Signs Monitor, Center Monitoring System, Telemetry  
Monitoring System, Pulse Oximeter, Defibrillator / Monitor  
and Accessories, Electrocardiograph, Anesthesia Machine  
and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic  
Equipment, Ultrasonic Transducer, Hematology Analyzer,  
Clinical Chemistry Analyzer, Microplate Reader, Microplate  
Washer for In-Vitro Diagnostic Use, Chemiluminescence  
Immunossay Analyzer, Flow Cytometer, Auto Sample  
Processing System, Auto Slide Maker and Stainer;) Reagents  
for Hematology Analyzer, Reagents for Clinical Chemistry  
Analyzer, Chemiluminescence Immunoassay Reagents,  
Chemiluminescence Immunoassav Calibrators and Controls;  
Disposable Anesthesia Mask, Reusable Anesthesia Mask,  
Respiratory Mask, Disposable Breathing Circuit, Reusable  
Breathing Circuit, Heat and Moisture Exchanger, Filter,  
Breathing Bag  
DUNS No: 65-467-1304

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Date of Issue: 2019-11-25



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# CERTIFICATE

No. QS6 044751 0135 Rev. 01

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

1203 Nanhuan Avenue, Guangming District, 518106, Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

Production of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag  
DUNS No: 54-459-5743

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Date of Issue: 2019-11-25



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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



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

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Date of Issue: 2020-08-20

Tina Israel  
Manager, US Certification Body,  
Medical and Health Services





America

# CERTIFICATE

No. QS 044751 0140 Rev. 02

**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

**Facility Scopes:**

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 Immunoassay 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

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Tina Israel  
Manager, US Certification Body,  
Medical and Health Services





America

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**Facility(ies)**

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Date of Issue: 2020-08-20

Tina Israel  
Manager, US Certification Body,  
Medical and Health Services

## Сертификат

Nasedchin Alexandr

компания: SRL Biosistem MLD

### Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
- Автоматический гематологический анализатор BC-5800
- Автоматический гематологический анализатор BC-3600

05 октября – 09 октября 2015

Технический тренер (инженер): Кузьмин Сергей

Дата: 09 октября 2015 года

Центр поддержки клиентов Mindray Medical Russia Ltd.



## Сертификат

Poiate Vitalie

компания: SRL Biosistem MLD

### Пройден технический тренинг по курсу:

- Автоматический гематологический анализатор BC-30s
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Дата: 09 октября 2015 года