EU Quality Management System Certificate CN23/00003444

The management system of

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

Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P.R. China
SRN Number: CN-MF-000014156

has been assessed and certified as meeting the requirements of

## MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 07 May 2024 until 27 June 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 December 2027.

Issue 4. Certified since 27 June 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

EU Quality Management System Certificate CN23/00003444, continued

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

## MDR EU Quality Management System certificate (Annex IX QMS)

Issue 4

Class IIa
MDA0306, MDS1009, MDS1005 Fluid Management System for supplying irrigation or suction (Model: HP100G, HP200G, HP200L, HP200D) (Basic UDI-DI: 69449040AB0651000589)

Class IIb
MDA0312, MDS1009 - EMDN: K020199
Electrosurgical Platform intended for use with monopolar and bipolar accessories for cutting and coagulating tissue
(Model: EP300, EP300B, EP300C, EP300D)
(B-UDI-DI: 69449040AB051100025W)

MDA0312, MDS1005, MDS1009- EMDN: K020299
Ultrasonic Surgical and Electrosurgical Energy Platform to provide power to drive electrosurgical instruments or ultrasonic surgical instruments for surgical treatment (Model: UP700, UP700B, UP700C, UP700D, UP500, UP500B, UP500C, UP500D, UP510, UP510B, UP510C, UP510D, UP703, UP705, UP710, UP713, UP715, UP Platinum)
(Basic UDI-DI: 69449040AB051100015U)

MDA0312, MDS1005- EMDN: K020201
Sterile single-use ultrasonic surgical instruments for soft tissue incisions and sealing vessels in open and endoscopic surgery
(Model: FC-14, FCH-14, FOK-14, FOM-14, PC-14, PCH-14, POK-14, POM-14, POS-14, PCT-14, FOS-14, FCT-14, FO-14, FC-23, FCH-23, FOK-23, FOM-23, PC-23, PCH-23, POK-23, POM-23, POS-23, PCT-23, FOS-23, FCT-23, FO-23, FC-36, FCH-36, FOK-36, FOM-36, PC-36, PCH-36, POK-36, POM-36, POS-36, PCT-36, FOS-36, FCT-36, FO-36, FC-45, FCH-45, FOK-45, FOM-45, PC-45, PCH-45, POK-45, POM-45, POS-45, PCT-45, FOS-45, FCT-45, FO-45)
(Basic UDI-DI: 69449040AB051100035Y)

EU Quality Management System Certificate CN23/00003444, continued

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

## MDR EU Quality Management System certificate (Annex IX QMS)

Issue 4

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation:
N/A

Certification is based on following reports: - CN/SZX/252762 - CTC 1.18
Authorized representative name and address (if relevant): Shanghai International Holding Corp. GmbH (Europe); Eiffestraße 80 20537 Hamburg, Germany
Previous certificate number: N/A
Change in between this certificate and previous one: Addition of device 'Sterile single-use ultrasonic surgical instruments'; Addition of models of UP510, UP510B, UP510C, UP510D, UP703, UP705, UP710, UP713, UP715, UP Platinum for device 'Ultrasonic Surgical and Electrosurgical Energy Platform'

EU Quality Management System Certificate CN23/00003444, continued

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

## MDR EU Quality Management System certificate (Annex IX QMS)

Issue 4

**Sites**

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P.R. China

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, Shenzhen, 518106, P.R. China

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

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www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 044751 0176 Rev. 04

**Manufacturer:**

**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

SRN Manufacturer - CN-MF-000014156

**Authorized Representative:**

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 044751 0176 Rev. 04

**Report No.:** SH2405511

**Preceding Certificate No.:** G10 044751 0176 Rev. 03

**Valid from:** 2024-11-21
**Valid until:** 2029-11-20

**Date of Initial Issuance:** 2019-11-21

**Issue date:** 2024-10-08

Christoph Dicks
Head of Certification/Notified Body


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www.zlg.de
BS-MDR-099

Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 044751 0176 Rev. 04

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120302 - VITAL SIGNS MONITORING INSTRUMENTS |
| **Intended Purpose:** | The patient monitor is intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120302 - VITAL SIGNS MONITORING INSTRUMENTS |
| **Intended Purpose:** | The Vital Signs Monitor is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120302 - VITAL SIGNS MONITORING INSTRUMENTS |
| **Intended Purpose:** | The Central Monitoring System is intended for monitoring vital sign information. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120306 - VITAL SIGNS TELEMETRY INSTRUMENTS (ECG, NIPB, EtCO2, SpO2, RESPIRATION,...) |
| **Intended Purpose:** | The Telemetry Monitor is intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters |

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z120503 - ELECTROCARDIOGRAPHS |
| **Intended Purpose:** | / |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | C020401 - EXTERNAL CARDIOVERSION DEFIBRILLATOR ELECTRODE PADS |
| **Intended Purpose:** | The external defibrillation paddles are intended for connecting with the patient and the defibrillator/monitor to perform defibrillation therapy and ECG detecting. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120302 - VITAL SIGNS MONITORING INSTRUMENTS |
| **Intended Purpose:** | The pulse oximeter is intended for continuously monitoring, spot checking, displaying, storing and transferring oxygen saturation and pulse rate of single patient. |




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Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 044751 0176 Rev. 04

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | V030102 - BODY TEMPERATURE MONITORING PROBES |
| **Intended Purpose:** | The temperature probe is intended for continuous patient temperature measurement and control applications. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120302 - VITAL SIGNS MONITORING INSTRUMENTS |
| **Intended Purpose:** | The SpO2 Sensor is intended for connecting with Mindray medical devices that support SpO2 measurements for measuring the arterial oxygen saturation and pulse rate of patients. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS |
| **Intended Purpose:** | The ventilator is intended for providing ventilation assistance and breathing support for patients. |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS |
| **Intended Purpose:** | The air compressor is intended for delivering dry and clean high pressure air to the ventilator or anesthesia machine and provide breathing support for patient. |

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z110401 - ULTRASOUND SCANNERS<br>Z110402 - ULTRASOUND PROBES |
| **Intended Purpose:** | / |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | Z110311 - DIRECT DIGITAL RADIOLOGY (DR) SYSTEMS |
| **Intended Purpose:** | The Radiography System is intended for performing radiographic X-ray examinations on all pediatric and adult patients. |

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES |
| **Intended Purpose:** | / |




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# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

## No. G10 044751 0176 Rev. 04

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS |
| **Intended Purpose:** | / |
| **Classification:** | Class IIa |
| **Device Group:** | V030101 - THERMOMETERS |
| **Intended Purpose:** | / |
| **Classification:** | Class IIa |
| **Device Group:** | Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS |
| **Intended Purpose:** | / |
| **Classification:** | Class IIb |
| **Device Group:** | Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS |
| **Intended Purpose:** | The Anesthesia System is a device used to deliver fresh gas, to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation through mechanical or manual ventilation. |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | -none- |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2019-11-21 | SH1905502 | - |
| 01 | 2021-10-28 | SH2005505 | - |
| 02 | 2024-02-22 | SH2205506 | Supplemented: Device(s)/group of device(s) added |
| 03 | 2024-07-05 | SH2105504/SH2305506 | Restricted: Product(s) reclassified<br>Supplemented: Device(s)/group of device(s) added |
| 04 | 2024-11-21 | SH2405511 | Renewal of certificate<br>Supplemented: Device(s)/group of device(s) added |




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# Certificate of Registration

This is to certify that the Quality Management System of

## Shenzhen Beacon Display Technology Co., Ltd.

**Unified Social Credit Code:** 91440300763457826J

**Operation Address:** 15F, Building 6, Hengda Shishang Huigu(East), Fulong Road, Dalang Subdistrict, Longhua, Shenzhen, 518109 China (Design, Sales); 1F, 2F, 3F, 4F, 5F, Building 6, Hualian Industrial Area, Xinshi Community, Dalang Street, Longhua District, Shenzhen, 518109 China(Production Site)

**Registered Address:** 15F, Building 6, Hengda Shishang Huigu(East), Fulong Road, Dalang Subdistrict, Longhua, Shenzhen, 518109 China

applicable to

Design, development, production and sales of LCD displays and human-machine interface products (control panels) for medical devices (products related to 3C requirements, limited to the scope of 3C certificates)

has been assessed and registered by NQA against the provisions of

**ISO 13485:2016**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number: **47645**

Issue Date: 13 May 2020
Previous Certificate Expiry: 13 May 2023
The Latest Audit Date: 05 May 2023
Reissue Date: 15 May 2023
Valid Until: 13 May 2026

UKAS MANAGEMENT SYSTEMS
0015

# DECLARATION OF CONFORMITY

**ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION**

## EU Representative

**SUNGO Europe B.V.**
**Fascinatio Boulevard 522, Unit 1.7,**
**2909VA Capelle aan den IJssel, The Netherlands**
**SRN: NL-AR-000000247**

## Conformity Assessment

**Conformity Assessment Procedure**
Annex II+III of Regulation (EU) 2017/745

**Applicable Standards**
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN 60601-1-2:2015
EN 60601-1:2006+A12:2014

**Remark**

*The declaration of conformity is valid in connection with the release technical document CE/MDR-Z119008-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

## Manufacturer

**Name:** Shenzhen Beacon Display Technology Co., Ltd.
**Address:** 15F, Building 6, Hengda Shishang Huigu(East), Fulong Road,Dalang Subdistrict, Longhua, Shenzhen, 518109 , P.R. China
**SRN:** CN-MF-000008774

## Product Information

**Name:** LCD Monitor
**Model:** See annex
**EMDN:** Z119008
**Basic UDI-DI:** 697002782001FH
**Classification:** Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745
**Intended Use:** The monitor is intended to be used in displaying and viewing digital images, for review and analysis by trained medical practitioners.

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 2021.10.11

Position: GM Place: Guangdong/China

# Annex

| Product Name | Model | EMDN | Basic UDI-DI |
|---|---|---|---|
| LCD Monitor | C22S+、C22SP+、C24S+、G22S+、G22SP+、G23S+、G23SP+、C32S+、C32SP+、G32S+、G32SP+、C53S+、C53SP+、G52S+、G52SP+、G53S+、G53SP+、C43W+、C44W+、C61W+、C81W+、C82W+、C83W+、C85W+、C86W+、C14ST、C14S、G11S、C22W、C22WT、C23W、C23WT、C24W、C24WT、M553T、M652T、M862T、M982T、E150、E190、E2421、E2422、E2721、S2421P、S271P、S272P、S273P、S2785P、S3281P、S3285P、S3180P、S421、S551、S5583P、S5580P、PV26、PV27、 S3221P、 S3181P、 U2221、 S1001T、M8681T、C411W、 HL2316SHA、 HL2316SHTB、HL2416SH、 HL2416SHT<br>S556、S556P、SP2421T、SP5581T、SP5581P、S3285P-3D、S3221P-3D、C1216W、C610W、C616W、C811W、C810RT、C810WT、C811RT、C811WT、HL2316SL、HL2416SL、C310S、C510S、G510S、C316S、C516S、G516S、G310S、G316S、C821W<br>E2420、S2720P、S2780P、S3282P、S3286P、S4385P、S5586P、S3286P-3D、SP6582P、SP6582T、SP3222T、SP3222P、P2740、P2780、P3280、C821WT、C822W、C822WT | Z119008 | 697002782001FH |

Signature: Date: 2020.10.11

Position: GM Place: Guangdong/China

Declaration of Conformity V2.0

# Declaration of Conformity

CE 1639

| | |
|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China |
| **Manufacturer SRN:** | CN-MF-000014156 |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80<br>20537 Hamburg, Germany |
| **Product:** | 4K 3D Video Endoscope |
| **Model:** | M 31030A, M 31000A, M 31030PA, M 31000PA, G 31030A, G 31000A, G 31030PA, G 31000PA |
| **Basic UDI-DI:** | 69449040AB065100068B |
| **Classification:** | IIa (According to Rule 7 of MDR Annex VIII) |
| **Conformity Assessment Route:** | Annex IX excluding CHAPTER II |
| **EMDN code:** | Z120290 |
| **Intended Purpose:** | The video endoscope is used together with the camera control unit for diagnostic and/or surgical procedures when endoscopic video support is required and is intended for short-term use. |

**We declare that the above-mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.**

| | |
|---|---|
| **References to CS:** | / |
| **Notified Body:** | SGS Belgium NV |
| **Notified Body No. :** | 1639 |
| **Identification of the Certificate:** | CN23/00003444 |
| **Start of CE-Marking:** | **2024-10-21** |

**I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.**

| | |
|---|---|
| **Place, Date of Issue:** | Shenzhen, 2024-10-21 |
| **Signature:** | |
| **Name of Authorized Signatory:** | Mr. Wang Xinbing |
| **Position Held in Company:** | Deputy Director, Technical Regulation |

Attachment of Declaration of Conformity: Applied Standards List-V2.0

# Applied Standards List

**Product:** 4K 3D Video Endoscope

**Model:** M 31030A, M 31000A, M 31030PA, M 31000PA, G 31030A, G 31000A, G 31030PA, G 31000PA

## Standards Applied:

| | |
|---|---|
| ISO 8600-1:2015 | Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements (ISO 8600-1:2015) |
| ISO 8600-3:2019 | Endoscopes - Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics (ISO 8600-3:2019) |
| ISO 8600-4:2023 | Endoscopes - Medical endoscopes and endotherapy devices - Part 4: Determination of maximum width of insertion portion (ISO 8600-4:2023) |
| ISO 8600-5:2020 | Optics and photonics -- Medical endoscopes and endotherapy devices -- Part 5: Determination of optical resolution of rigid endoscopes with optics (ISO 8600-5:2020) |
| ISO 8600-7:2012 | Endoscopes - Medical endoscopes and endotherapy devices - Part 7: Basic requirements for medical endoscopes of wate r- resistant type (ISO 8600-7:2012) |
| EN ISO 20417:2021 | Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021) |
| EN ISO 15223-1:2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) |
| EN 60601-1:2006/A2:2021 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| EN 60601-1-2:2015/A1:2021 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |
| EN 60601-1-6:2010/A2:2021 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| EN 62366-1:2015/A1:2020 | Processing of health care products - Information to be provided by the Medical devices - Part 1: Application of usability engineering to medical devices |
| EN ISO 17664-1:2021 | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021) |

| | |
|---|---|
| EN 60601-2-18:2015 | Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment |
| EN ISO 14971:2019/A11:2021 | EN ISO 14971:2019/A11:2021 Medical devices - Application of risk management to medical devices (ISO 14971:2019) |
| EN ISO 10993-1:2020 | Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2020) |
| ISO 11135:2014 | Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices |
| ISO 17665-1:2006 | Sterilization of health-care products -Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices |
| EN ISO 10993-5:2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) |
| EN ISO 10993-10:2023 | Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021) |
| EN ISO 10993-11:2018 | Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017) |
| EN ISO10993-23:2021 | Biological evaluation of medical devices — Part 23: Tests for irritation (ISO10993-23:2021) |
| EN ISO 10993-7:2008/A1:2022 | Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants (ISO 10993-7:2008/A1:2019) |
| ISO 13485: 2016 | Medical devices-Quality management systems-Requirements for regulatory purposes |
| EN 62304:2006/A1:2015 | Medical device software - Software life-cycle processes |

Declaration of Conformity V1.0

CE 1639

# Declaration of Conformity

| | |
|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China |
| **Manufacturer SRN:** | CN-MF-000014156 |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany |
| **Product:** | Electrosurgical Platform |
| **Model:** | EP300, EP300B, EP300C, EP300D |
| **Basic UDI-DI:** | 69449040AB051100025W |
| **Classification:** | IIb (According to Rule 9 of MDR Annex VIII) |
| **Conformity Assessment Route:** | Annex IX excluding CHAPTER II |
| **EMDN code:** | K020199 |
| **Supplementary information:** | / |
| **Intended purpose** | The Electrosurgical platform provides power to drive electrosurgical instruments for surgical treatment. |

**We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.**

| | |
|---|---|
| **References to CS:** | / |
| **Notified Body:** | SGS Belgium NV |
| **Notified Body No. :** | 1639 |
| **Identification of the Certificate:** | CN23/00003444 |
| **Start of CE-Marking:** | 2023-6-27 |

**I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.**

**Place, Date of Issue:** Shenzhen 2023-6-27

**Signature:**

**Name of Authorized Signatory:** Mr. Wang Xinbing
**Position Held in Company:** Deputy Director, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V1.0

# Applied Standards List

**Product:** Electrosurgical Platform

**Model:** EP300, EP300B, EP300C, EP300D

## Standards Applied:

| | |
|---|---|
| **EN ISO 14971:2019:A11:2021** | Medical devices – Application of risk management to medical devices |
| EN ISO 20417:2021 | Medical devices - Information to be supplied by the manufacturer |
| **EN ISO 15223-1:2021** | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements |
| **EN60601-1:2006/ A1:2013** | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| **EN60601-1-2:2015** | Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| **EN 60601-1-6: 2010/A1:2015** | Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability |
| **EN 62304:2006/A1:2015** | Medical device software - Software life-cycle processes |
| **EN 62366-1:2015** | Medical devices -- Application of usability engineering to medical devices |
| **EN IEC 60601-2-2:2018** | Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories |
| **EN 60601-1-8:2007/A2:2021** | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |

Declaration of Conformity V2.0

# Declaration of Conformity

CE 0123

| | |
|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China |
| **Manufacturer SRN:** | CN-MF-000014156 |
| **EC-Representative** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80 20537 Hamburg, Germany |
| **Product:** | Endoscope Light Source |
| **Model:** | HB500R, HB500R-TEC |
| **Basic UDI-DI:** | 69449040AB065100088F |
| **Classification:** | IIa (According to Rule 10 of MDR Annex VIII) |
| **Conformity Assessment Route:** | Annex IX excluding CHAPTER II |
| **EMDN code** | Z120204 |
| **GMDN code:** | 35158 |
| **Supplementary information** | / |

**We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.**

| | |
|---|---|
| **References to CS:** | / |
| **Notified Body:** | TÜV SÜD Product Service GmbH Ridlerstraße 65<br>80339 München, Germany. |
| **Notified Body No. :** | 0123 |
| **EC Certificate No.:** | G10 044751 0176 |
| **Start of CE-Marking:** | **2023-6-29** |

**I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.**

**Place, Date of Issue:** Shenzhen, 2024-4-10

**Signature:** .....

**Name of Authorized Signatory:** Mr. Wang Xinbing

**Position Held in Company:** Deputy Director, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V2.0

# Applied Standards List

**Product:** Endoscope Light Source

**Model:** HB500R, HB500R-TEC-

## Standards Applied:

| | |
|---|---|
| **EN ISO 14971:2012/A11:2021** | Medical devices – Application of risk management to medical devices |
| **EN ISO 20417:2021** | Medical devices - Information to be supplied by the manufacturer |
| **EN ISO 15223-1:2021** | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements |
| **EN 60601-1:2006/A2:2021** | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| **EN 60601-1-2:2015/A1:2021** | Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| **EN 60601-1-6:2010/A2:2021** | Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability |
| **EN 62304:2006/A1:2015** | Medical device software - Software life-cycle processes |
| **EN 62366-1:2015/A1:2020** | Medical devices -- Application of usability engineering to medical devices |
| **EN 60601-2-18: 2015** | Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment |
| **EN 62471:2008** | Photobiological safety of lamps and lamp systems. |
| **EN 60825-1:2014/A11:2021** | Safety of laser products – Part 1: Equipment classification and requirements. |

# Declaration of Conformity

CE 0123

| | |
|---|---|
| **Manufacturer:** | Nanjing Mindray Bio-Medical Electronics Co., Ltd.<br>666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu, P.R.China |
| **Manufacturer SRN:** | CN-MF-000019806 |
| **EC-Representative** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80 20537 Hamburg, Germany |
| **Product:** | Insufflator |
| **Model:** | HS-50F, HS-50V, HS-50H, HS-50S, HS-30S |
| **Basic UDI-DI:** | 69483505AB06510006CR |
| **Classification:** | IIa (According to Rule 12 of MDR Annex VIII) |
| **Conformity Assessment Route:** | Annex IX excluding CHAPTER II |
| **GMDN code:** | 16849 |
| **CND code:** | Z120290 |
| **Intended Purpose:** | The Insufflator for laparoscopy has been designed for insufflation of abdominal cavity to facilitate laparoscopic observation, diagnosis and treatment. |

**We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.**

| | |
|---|---|
| **References to CS:** | / |
| **Notified Body:** | TÜV SÜD Product Service GmbH Ridlerstraße 65<br>80339 München, Germany. |
| **Notified Body No. :** | 0123 |
| **Identification of the Certificate:** | G10 070744 0019 |
| **Start of CE-Marking:** | 2019-08-27 |

**I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Management Representative of Nanjing Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.**

| | |
|---|---|
| **Place, Date of Issue:** | Nanjing, 2024-04-25 |
| **Signature:** | Zhai Pei |
| **Name of Authorized Signatory:** | Mr. Zhai Pei |
| **Position Held in Company:** | Manager, Technical Regulation |

Attachment of Declaration of Conformity: Applied Standards List-V2.0

# Applied Standards List

**Product:** **Insufflator**

**Model:** **HS-50F, HS-50V, HS-50H, HS-50S, HS-30S**

## Standards Applied:

| | |
|---|---|
| **EN ISO 14971:2019/A11:2021** | Medical devices – Application of risk management to medical devices |
| **EN ISO 20417:2021** | Information supplied by the manufacturer of medical devices |
| **EN ISO 15223-1:2021** | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements |
| **EN60601-1:2006/ A1:2013** | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| **EN 60601-2-18:2015** | Medical electrical equipment – Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment |
| **EN 60601-1-2:2015/A1:2021** | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. |
| **IEC 60601-1-6:2010 /A1:2013/A2:2020** | Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability |
| **EN ISO 10993-1:2020** | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| **IEC 62366-1:2015/A1:2020** | Medical devices -- Application of usability engineering to medical devices |
| **EN ISO 17664-1:2021** | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices |
| **IEC 62304:2015** | Medical device software-Software life cycle processes |
| **ISO 80369-7:2021** | Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications |
| **ISO 10993-5:2009** | Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity |
| **ISO 10993-10:2021** | Biological evaluation of medical devices Part 10: Tests for skin sensitization |
| **ISO 10993-23:2021** | Biological evaluation of medical devices Part 23: Tests for irritation |
| **ISO 10993-11:2017** | Biological evaluation of medical devices Part 11: Tests for systemic toxicity |
| **ISTA 2A:2011** | PACKAGED-PRODUCTS 150 LB (68 KG) OR LESS |

Declaration of Conformity V3.0

# Declaration of Conformity

CE

| | |
|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,<br>Nanshan, Shenzhen, 518057, P. R. China |
| **Manufacturer SRN:** | CN-MF-000014156 |
| **EC-Representative** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80 20537 Hamburg, Germany |
| **Product:** | Endoscope Camera System |
| **Model:** | UX5/UX5–TEC/UX5–NOR/UX5–SIM/UX3/UX3–TEC/<br>UX3–NOR/UX3–SIM/UX1/UX1-TEC/UX1-NOR/UX1-SIM/<br>UX4/UX410/UX420/UX430/UX450/UX460/UX470/UX5/<br>UX510/UX520/UX530/UX550/UX560/UX570/UX5–SIM/<br>UX5–NOR/UX5–TEC/UX7/UX7-TEC/UX7-NOR/ UX7-SIM |
| **Basic UDI-DI:** | 69449040AB065100078D |
| **Classification:** | I(According to Rule 13 of MDR Annex VIII) |
| **Conformity Assessment Route:** | Article 52.7 |
| **EMDN code:** | Z120204 |
| **GMDN code:** | 35958 |
| **Supplementary information** | TV-300/TV-300T(220V)/TV-300T(110V)/TV-500/<br>TV-500T(220V)/TV-500T(110V)/TP-MFS Mobile Trolley;<br>CH5-SW100/CH5-SW110/CH5-SR100/CH5-SR110/<br>CH3-SW100/CH3-SW110 camera head |

**We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.**

| | |
|---|---|
| **References to CS:** | / |
| **Start of CE-Marking:** | 2023-6-29 |

**I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.**

| | |
|---|---|
| **Place, Date of Issue:** | Shenzhen, 2024-12-31 |
| **Signature:** | |
| **Name of Authorized Signatory:** | Mr. Wang Xinbing |
| **Position Held in Company:** | Deputy Director, Technical Regulation |

Attachment of Declaration of Conformity: Applied Standards List-V3.0

# Applied Standards List

| | |
|---|---|
| **Product:** | Endoscope Camera System |
| **Model:** | UX5/UX5–TEC/UX5–NOR/UX5–SIM/UX3/UX3–TEC/ UX3–NOR/UX3–SIM/UX1/UX1-TEC/UX1-NOR/UX1-SIM/ UX4/UX410/UX420/UX430/UX450/UX460/UX470/UX5/ UX510/UX520/UX530/UX550/UX560/UX570/UX5–SIM/ UX5–NOR/UX5–TEC/UX7/UX7-TEC/UX7-NOR/ UX7-SIM |

## Standards Applied:

| | |
|---|---|
| **EN ISO 14971:2012/A11:2021** | Medical devices – Application of risk management to medical devices |
| **EN ISO 20417:2021** | Medical devices - Information to be supplied by the manufacturer |
| **EN ISO 15223-1:2021** | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements |
| **EN 60601-1:2006/A2:2021** | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| **EN 60601-1-2:2015/A1:2021** | Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| **EN 60601-1-6:2010/A2:2021** | Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability |
| **EN 62304:2006/A1:2015** | Medical device software - Software life-cycle processes |
| **EN 62366-1:2015/A1:2020** | Medical devices -- Application of usability engineering to medical devices |
| **EN ISO 17664-1:2021** | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices |
| **EN 60601-2-18: 2015** | Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment |

Declaration of Conformity V1.0

# Declaration of Conformity

CE 1639

| | |
|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China |
| **Manufacturer SRN:** | CN-MF-000014156 |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80<br>20537 Hamburg, Germany |
| **Product:** | Fluid Management System |
| **Model:** | HP100G, HP200G, HP200L, HP200D |
| **Basic UDI-DI:** | 69449040AB0651000589 |
| **Classification:** | IIa (According to Rule 12 of MDR Annex VIII) |
| **Conformity Assessment Route:** | Annex IX excluding CHAPTER II |
| **EMDN code:** | Z120190 |
| **Intended Purpose:** | The product is intended for irrigation and/or suction during endoscopic examination and surgery. |
| **Supplementary information:** | Included are following reusable irrigation tubing set: IR100R, following reusable suction tubing set: SU100R and following Two-Pedal Footswitch-Fluid Management System: FS200. |

**We declare that the above-mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.**

| | |
|---|---|
| **References to CS:** | / |
| **Notified Body:** | SGS Belgium NV |
| **Notified Body No. :** | 1639 |
| **Identification of the Certificate:** | / |
| **Start of CE-Marking:** | 2023-9-13 |

**I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.**

| | |
|---|---|
| **Place, Date of Issue:** | Shenzhen 2023.9.13 |
| **Signature:** | |
| **Name of Authorized Signatory:** | Mr. Wang Xinbing |
| **Position Held in Company:** | Deputy Director, Technical Regulation |

Attachment of Declaration of Conformity: Applied Standards List-V1.0

# Applied Standards List

**Product:** Fluid Management System

**Model:** HP100G, HP200G, HP200L, HP200D

## Standards Applied:

| | |
|---|---|
| EN ISO 14971:2019/A11:2021 | Medical devices - Application of risk management to medical devices (ISO 14971:2019) |
| EN ISO 20417:2021 | Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021) |
| EN ISO 15223-1:2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) |
| EN 60601-1:2006/A1:2013 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| EN 60601-1-2:2015 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |
| EN 60601-1-8:2007/A1:2013 | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| EN 60601-1-6:2010 /A1:2015 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| EN 62366-1:2015 | Medical devices - Part 1: Application of usability engineering to medical devices |
| EN 62304:2006/A1:2015 | Medical device software - Software life-cycle processes |
| EN ISO 10993-1:2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 17664-1:2021 | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021) |
| EN ISO 13485:2016/A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |