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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-10-08

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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

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.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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

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 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:	/

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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

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 Supplemented: Device(s)/group of device(s) added
04	2024-11-21	SH2405511	Renewal of certificate Supplemented: Device(s)/group of device(s) added

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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: 2024.10.11

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 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 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 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. 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:	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 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. 666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu, P.R.China
Manufacturer SRN:	CN-MF-000019806
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) 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 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

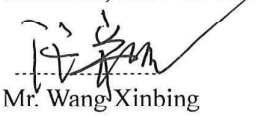
CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-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:	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
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/ TV-500T(220V)/TV-500T(110V)/TP-MFS Mobile Trolley; CH5-SW100/CH5-SW110/CH5-SR100/CH5-SR110/ 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. 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:	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)

Declaration of Conformity *V2.0*

Declaration of Conformity

CE 0123

Manufacturer:	Nanjing Mindray Bio-Medical Electronics Co., Ltd. 666# Middle Zhengfang Road, Jiangning 211111 Nanjing, Jiangsu, People' s Republic of China.
Manufacturer SRN:	CN-MF-000019806
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Rigid Endoscope
Model:	M 01030A、M 01000A、M 01030PA、M 01000PA、G 01030A、G 01000A、G 01030PA、G 01000PA、M 00530A、G 00530A、M 00500A、G 00500A、M 10530A、G 10530A、M 10500A、G 10500A、M 00530PA、G 00530PA、M 00500PA、G 00500PA、M 10530PA、G 10530PA、M 10500PA、G 10500PA
Basic UDI-DI:	69483505AB06510005CP
Classification:	IIa (According to Rule 7 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	12291、35398
CND code:	Z12029009、Z12029017

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 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	G10 070744 0019
Start of CE-Marking:	2023-06-30

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

Place, Date of Issue:	**Nanjing, 2023-06-30**
Signature:	Zhai Pei
Name of Authorized Signatory:	Mr. ZhaiPei
Position Held in Company:	Manager, Technical Regulation

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

Applied Standards List

Product: **Rigid Endoscope**

Model: **M 01030A、M 01000A、M 01030PA、M 01000PA、G 01030A、G 01000A、G 01030PA、G 01000PA、M 00530A、G 00530A、M 00500A、G 00500A、M 10530A、G 10530A、M 10500A、G 10500A、M 00530PA、G 00530PA、M 00500PA、G 00500PA、M 10530PA、G 10530PA、M 10500PA、G 10500PA**

Standards Applied:

ISO 14971:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)
ISO 15223-1-2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
EN 60601-1:2006/A2:2021	Medical Electrical Equipment, Part 1: General Requirements for Safety
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 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 8600-3:2019	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics
ISO 8600-4:2014	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 4: Determination of maximum width of insertion portion
ISO 8600-5:2020	Optics and photonics -- Medical endoscopes and endotherapy devices -- Part 5: Determination of optical resolution of rigid endoscopes with optics
ISO 8600-1:2015	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 1: General requirements
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
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

IEC 60601-1-9-2020

Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design