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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
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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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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:	/

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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

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