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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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. 01

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 and certification regulation of 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. 01

Report No.: SH2005505

Preceding Certificate No.: G10 044751 0176 Rev. 00

Valid from: 2021-10-28
Valid until: 2024-11-20

Date of Initial Issuance: 2019-11-21

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-10-28

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

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

Classification:	IIa
Device Group:	Z120503 - ELECTROCARDIOGRAPHS
Intended Purpose:	/

Classification:	IIb
Device Group:	Z120305 - DEFIBRILLATORS
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:	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:	IIa
Device Group:	V030102 - PROBES, TEMPERATURE MONITORING
Intended Purpose:	/

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

Classification:	IIb
Device Group:	Z120301 - INSTRUMENTS FOR ANESTHESIA AND PULMONARY VENTILATION SUPPORT
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:	IIa
Device Group:	Z110401 - ULTRASOUND SCANNERS
Intended Purpose:	/

Classification:	IIb
Device Group:	Z110311 - DIRECT DIGITAL X-RAY SYSTEMS
Intended Purpose:	The Radiography System is intended for performing radiographic X-ray examinations on all pediatric and adult patients.

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

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The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report
00	2019-11-21	SH1905502

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