CE 0123

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
EC-Representative SRN:	DE-AR-000000001
Product:	Patient monitor
Model:	uMEC 30 / uMEC 60 / uMEC 70 / uMEC 80 / uMEC 100 / uMEC 120 / uMEC 150
Basic UDI-DI:	69449040AB010000473Q
Classification:	IIb (According to Rule 10 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	33586
EMDN code:	Z120302
Intended Purpose:	The Vital Signs Monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters.

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 044751 0176 Rev. 06
Start of CE-Marking:	2023-7-7

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, 2025.9.22
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

Applied Standards List

Product: **Patient monitor**

Model: **uMEC 30 / uMEC 60 / uMEC 70 / uMEC 80 / uMEC 100 / uMEC 120 / uMEC 150**

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 with medical devices
EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Prat 2: Non-critical medical devices
EN 60601-1:2006+A1:2013+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/A1:2015/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007/A1:2013/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
EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 60601-2-27:2014	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN IEC 80601-2-30:2019	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN 60601-2-34:2014	Medical electrical equipment Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
EN IEC 80601-2-49:2019	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
EN ISO 80601-2-55:2018	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

EN ISO 80601-2-56:2017/A1:2020	Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN ISO 80601-2-61:2019	Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN ISO 81060-2:2019/A1:2020	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN 62304:2006/A1:2015	Medical device software - Software lifecycle processes
EN 62366-1:2015+A1:2020	Medical devices – Application of usability engineering to medical devices