



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 Annex IX excluding CHAPTER II
Route:
GMDN code: 33586
CND code: Z120302
Intended Purpose: The patient monitor is 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
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, 2023.7.7

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 14971:2019/A11:2021	ISO	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 — Part 2: Non-critical medical devices
EN 60601-1:2006+A1:2013+A2:2021	60601-1	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	60601-1-2	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	60601-1-6	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	60601-1-8	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	80601-2-56	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