

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China
Shanghai International Holding Corp. GmbH (Europe)

EC-Representative: Eiffestraße 80
20537 Hamburg, Germany

Product: Patient Monitor (Including Accessories)

Model: ePM 10/ePM 10A/ePM 10C/ePM 12/ePM 12A/ePM 12C/
ePM 15/ePM 15A/ePM 15C

Classification: II b (According to Rule 10 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding (4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

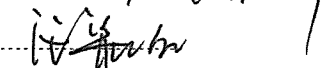
List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany

Notified Body No. : 0123

Start of CE-Marking: 2018-12-29

Place, Date of Issue: Shenzhen, 2018.12.29

Signature: 

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

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ePM 15/ePM 15A/ePM 15C

Applied Standards:

EN ISO 14971:2012 Medical devices – Application of risk management to medical devices

EN 1041:2008 Information supplied by the manufacturer with medical devices

ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EN ISO 10993-1:2009/AC:2010 **ISO** Biological evaluation of medical devices - Part 1: Evaluation and testing

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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 compatibility - Requirements and tests

IEC 60601-1-6:2013 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

IEC 60601-1-8:2012 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

IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30:2013	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-34:2011	Medical electrical equipment - Part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
IEC 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-55:2011	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56:2009	Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 81060-2:2013	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
IEC 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices
IEC 62304:2015	Medical device software - Software life cycle processes