

Declaration of Conformity-V1.0

# Declaration of Conformity 0123

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

**Manufacturer:**

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

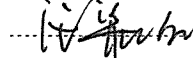
**Start of CE-Marking:**

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

**Product:** Patient Monitor (Including Accessories)

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**Applied Standards:**

<b>EN ISO 14971:2012</b>	Medical devices – Application of risk management to medical devices
<b>EN 1041:2008</b>	Information supplied by the manufacturer with medical devices
<b>ISO 15223-1:2016</b>	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
<b>EN 10993-1:2009/AC:2010</b>	<b>ISO</b> Biological evaluation of medical devices - Part 1: Evaluation and testing
<b>EN ISO 10993-5:2009</b>	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
<b>ISO 10993-10:2010</b>	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
<b>EN 60601-1: 2006+A1:2013</b>	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
<b>EN 60601-1-2:2015</b>	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
<b>IEC 60601-1-6:2013</b>	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
<b>IEC 60601-1-8:2012</b>	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
<b>IEC 60601-2-25:2011</b>	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

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