

# 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

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80  
20537 Hamburg, Germany

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

**Model:** uMEC6/uMEC7/uMEC10/uMEC12/uMEC15/uMEC15S

**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:**

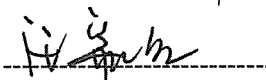
List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

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

**Notified Body No. :** 0123

**Start of CE-Marking:** 2016-3-31

**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)****Model:**

uMEC6/uMEC7/uMEC10/uMEC12/uMEC15/uMEC15S

**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

**EN 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:**

Biological evaluation of medical devices - Part 1: Evaluation and testing

**2009/AC:2010****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

**EN 60601-1-6:2013**

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

**EN 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

**EN 60601-2-27:2006/AC:2006**

Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

**EN 60601-2-30:2000**

Medical electrical equipment -- Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

**EN 60601-2-34:2000**

Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment

**EN 60601-2-49:2001**

Medical electrical equipment - Part 2-49: Particular requirements for the safety 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

**EN 62366:2008**

Medical devices - Application of usability engineering to medical devices

**EN 62304:2006/AC:2008**

Medical device software - Software life cycle processes.