# Declaration of Conformity

**Declaration of Conformity-V1.0**

CE 0123

# 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 Monitors (Including Accessories)

**Model:** **uMEC6、uMEC7、uMEC10、uMEC12**

**Classification:** IIb（According to Rule 10 of MDD Annex IX）

**Conformity Assessment Route:** MDD Annex Ⅱ excluding (4)

**We herewith declare 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

Digitally signed by Prodan Sveatoslav
Date: 2021.07.05 15:40:30 EEST
Reason: MoldSign Signature
Location: Moldova

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

**Place, Date of Issue:** Shenzhen 2016.3.31

**Signature:** _____

**Name of Authorized Signatory:** Mr. Tan Chuanbin

**Position Held in Company:** Manager, Technical Regulation

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|---|---|
| **Product:** | **Patient Monitors** |
| **Model:** | **uMEC6、uMEC7、uMEC10、uMEC12** |
| **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 15223-1-2012** | 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** | Biological evaluation of medical devices - Part 1: Evaluation and testing |
| **EN60601-1: 2006 /AC:2010** | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| **EN60601-1-2: 2007/AC:2010** | 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** | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability |
| **EN 60601-1-8:2007/AC:2010** | 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 |

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|---|---|
| **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.

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

Model: **uMEC6、uMEC7、uMEC10、uMEC12**

**We herewith declare that the above mentioned products meet the provisions of the Council Directive 2011/65/EU. All supporting documentations are retained under the premises of the manufacturer.**

**Standards Applied:**
EN 50581:2012.

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

**Place, Date of Issue:** Shenzhen 2016.3.31

**Signature:** .....

**Name of Authorized Signatory:** Mr. Tan Chuanbin

**Position Held in Company:** Manager, Technical Regulation