Declaration of Conformity V1.0

# Declaration of Conformity

CE 0123

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|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,<br>Nanshan, Shenzhen, 518057, P. R. China |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80<br>20537 Hamburg, Germany |
| **Product:** | Patient Monitor (Including Accessories) |
| **Model:** | iMEC8、iMEC10、iMEC12 |
| **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 concerning 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:** 2011-8-31

**Place, Date of Issue:** Shenzhen, 2011-8-31

**Signature:** .....

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

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

Attachment of Declaration of Conformity: Applied Standards List-V1.0

# Applied Standards List

**Product:** **Patient Monitor**

**Model:** **iMEC8, iMEC10, iMEC12**

## Standards Applied:

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| **EN ISO 14971: 2009** | Medical devices - Application of risk management to medical devices |
| **EN 1041: 2008** | Information supplied by the manufacturer with medical devices |
| **EN 980: 2008** | Graphical symbols for use in the labeling of medical devices |
| **IEC/TR 60878: 2003** | Graphical symbols for electrical equipment in medical practice |
| **ISO 1000: 1992+A1:1998** | SI units and recommendations for the use of their multiples and of certain other units |
| **EN ISO 10993-1: 2009/AC:2010** | Biological evaluation of medical devices - Part 1: Evaluation and testing |
| **EN 60601-1: 1990+A1:1993+A2:1995** | Medical electrical equipment - Part 1: General requirements for safety |
| **EN 60601-1-1: 2001** | Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems |
| **EN 60601-1-2: 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 60601-1-4: 1996+A1:1999** | Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems |
| **EN 60601-1-6: 2007/AC:2010** | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |

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| 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 |
| EN 60601-2-25: 1995+A1:1999 | Particular requirements for safety Specifications for electrocardiographs |
| 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 60601-2-30: 2004 | 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 |
| ANSI/AAMI EC13: 2002 | Cardiac monitors, heart rate meters, and alarms |
| EN 1060-1: 1995+A2:2009 | Specification for Non-invasive sphygmomanometers - Part 1: General requirements |
| EN1060-3: 1997+A2:2009 | Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems |
| EN 1060-4: 2004 | Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers |
| EN ISO 21647: 2009 | Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors |
| EN ISO 9919: 2009 | Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use |

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| **EN 12470-4: 2000+A1:2009** | Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement |
| **EN 62304: 2006/AC:2008** | Medical device software - Software lifecycle processes |
| **EN 62366: 2008** | Medical devices - Application of usability engineering to medical devices |

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

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

**Model:** iMEC8、iMEC10、iMEC12

**Conformity Assessment Route:** R&TTE Annex III

**We herewith declare that the above mentioned products meet the provisions of the Council Directive 1995/5/EC R&TTE Device. All supporting documentations are retained under the premises of the manufacturer.**

**Standards Applied:**

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|---|---|
| ☒EN 300 328 V1.7.1 | ☒EN 60601-1-2: 2007/AC:2010 |
| ☒EN 301 489-17 V2.1.1 | ☒EN 60601-1: 1990+A1:1993+A2:1995 |
| ☒EN 301 489-1 V1.8.1 | ☒EN 62311:2008 |

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

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