

# 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:** Pulse Oximeter (Including accessories)  
**Model:** PM-60  
**Classification:** II b ( 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:**

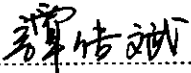
List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

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

**Notified Body No. :** 0123

**Start of CE-Marking:** 2007-07-27

**Place, Date of Issue:** Shenzhen, 2011-10-14

**Signature:** 

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

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

## Applied Standards List

**Product:** Pulse Oximeter

**Model:** PM-60

### Applied Standards:

EN ISO 14971: 2007	Medical devices - Application of risk management to medical devices
EN1041: 1998	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
ISO15223: 2000+A1:2002+A2:2004	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
ISO1000: 1992+A1:1998	SI units and recommendations for the use of their multiples and of certain other units
EN ISO 10993-1: 2009	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	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	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8: 2007	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 ISO 9919: 2009	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Attachment of Declaration of Conformity: Applied Standards List – V11.0

<b>EN1789: 2007</b>	Medical vehicles and their equipment - Road ambulances
<b>EN 62304: 2006</b>	Medical device software - Software lifecycle processes
<b>EN 62366: 2008</b>	Medical devices - Application of usability engineering to medical devices

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