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:	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

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