Declaration of Conformity-V12.0

Declaration of Conformity

CE 0123

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: Ⅱb （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: **2007-07-27**

Place, Date of Issue: Shenzhen, 2018.12.29

Signature: ----------

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Product: **Pulse Oximeter (Including accessories)**

Model: PM-60

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, labeling and information to be supplied
EN ISO 10993-1: 2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 60601-1: 2006/A1:2013	Medical electrical equipment - Part 1: General requirements for safety
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
IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 80601-2-61:2011	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 62304: 2006	Medical device software - Software lifecycle processes
EN 62366: 2008	Medical devices - Application of usability engineering to medical devices
EN 1789: 2014	Medical Vehicles and Their Equipment - Road Ambulances
IEC 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