Declaration of Conformity V3.0

# 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:** Digital Ultrasonic Diagnostic Imaging System

**Model:** DP-10/DP-10T/DP-11/DP-15/DP-18

**Supplementary information:** Included are following transducers:35C20EA, 35C50EB, 65C15EA, 65EC10EB, 75L38EB, 75L60EA and the following needle-guided brackets: NGB-001, NGB-002, NGB-003, NGB-004, NGB-005, NGB-012

**Classification:** IIa （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: 2011-9-15**

**Place, Date of Issue:** Shenzhen, 2017-12-29

**Signature:** .....

**Name of Authorized Signatory:** Mr. Wang Xinbing

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

**Attachment of Declaration of Conformity: Applied Standards List-V3.0**

# Applied Standards List

**Product:** Digital Ultrasonic Diagnostic Imaging System

**Model:** **DP-10/DP-10T/DP-11/DP-15/DP-18**

**Standards Applied:**

| | |
|---|---|
| **EN ISO 14971: 2012** | Medical devices – Application of risk management to medical devices |
| **EN 1041: 2008** | Information supplied by the manufacturer of medical devices |
| **EN ISO 15223-1: 2012** | Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirements |
| **EN 60601-1:2006/A1:2013** | Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance |
| **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 60601-1-6: 2010** | Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -collateral standard: usability |
| **EN 60601-2-37: 2008** | Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment |
| **EN ISO 10993-1: 2009/AC:2010** | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| **EN 62366:2008** | Medical devices -- Application of usability engineering to medical devices |
| **EN 62304:2006 /AC:2008** | Medical device software -- Software life cycle processes |
| **EN ISO 17664:2004** | Sterilization of medical devices —Information to be provided by the manufacturer for the processing of resterilizable medical devices. |