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, Nanshan, Shenzhen, 518057, P. R. China |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80<br>20537 Hamburg, Germany |
| **Product:** | Diagnostic Ultrasound System |
| **Model:** | Z50, Z50T, Z50BW |
| **Supplementary information:** | Included are following transducers: 35C50EA, 35C50EB, 65EC10EA, 65EC10EB, 75L38EA, 75L38EB, 65C15EA, 35C20EA, 10L24EA, D6-2EA and following needle-guided brackets: NGB-004, NGB-005, NGB-016, NGB-001, NGB-002, NGB-003. |
| **Classification:** | IIa （According to Rule 10 of MDD Annex IX） |
| **Conformity Assessment Route:** | MDD Annex II excluding(4) |
| **GMDN code:** | 40761 |

**We 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. This declaration of conformity is issued under the sole responsibility 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:** **2019-07-09**

**Place, Date of Issue:** Shenzhen , 2019.7.9

**Signature:** .....

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

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

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

# Applied Standards List

**Product:** **Diagnostic Ultrasound System**

**Model:** **Z50, Z50T, Z50BW**

## Standards Applied:

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|---|---|
| **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 15223-1：2016** | 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 |
| **EN60601-1-2:2015** | Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests |
| **EN 60601-1-6:2010 /A1:2015** | Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability |
| **EN 60601-2-37:2008/A1:2015** | 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 62304:2006/A1:2015** | Medical device software - Software life-cycle processes |
| **EN 62366-1:2015** | Medical devices -- Application of usability engineering to medical devices |
| **EN ISO 17664:2017** | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices |