Declaration of Conformity V5.0

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: Diagnostic Ultrasound System

Model: Z5, Z5BW

Supplementary information: Included are following transducers: 35C50EA, 35C50EB, 65EC10EA, 65EC10EB, 75L38EA, 75L38EB, 65C15EA, 35C20EA, 10L24EA and following needle-guided brackets: NGB-004, NGB-005, NGB-0016, NGB-001, NGB-002, NGB-003.

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: 2012-9-27

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-V5.0

Applied Standards List

Product: **Diagnostic Ultrasound System**

Model: **Z5, Z5BW**

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
EN60601-1-2:2007/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 62304:2006/AC:2008	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices -- Application of usability engineering to medical devices
EN ISO 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices