Declaration of Conformity V4.0

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: M7 Premium

Supplementary information: Included are following transducers: C5-2s, L14-6s, P4-2s, V10-4s, V10-4Bs, 4CD4s, P7-3s, 7L4s, 6C2s, L7-3s, 7L5s, P12-4s, L12-4s, L14-6Ns, CW2s, P7-3Ts, 7LT4s, CW5s, L16-4Hs, C6-2Gs, 6LB7s, C11-3s, L9-3s, SP5-1s and following needle-guided brackets: NGB-004, NGB-005, NGB-007, NGB-009, NGB-010, NGB-011, NGB-015, NGB-016, NGB-018, NGB-024, NGB-034

Classification: IIa （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 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: **2017-05-13**

Place, Date of Issue: Shenzhen, 2018.12.29

Signature: .....

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V4.0

Applied Standards List

Product: **Diagnostic Ultrasound System**

Model: **M7 Premium**

Standards Applied:

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-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	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
IEC/EN 60601-2-18: 1996+A1 2000	Medical electrical equipment—Part2: Particular requirements for the safety of endoscopic equipment