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:	Digital Ultrasonic Diagnostic Imaging System
Model:	DP-10/DP-10T/DP-11/DP-15/DP-18
Supplementary information:	Included are following transducers:35C50EB, 65EC10EB, 75L38EB, 65C15EA, 35C20EA, 75L53EA and following needle-guided brackets: NGB-001, NGB-002, NGB-003, NGB-004, NGB-005, NGB-007.
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: 2012-02-21

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-V5.0

Applied Standards List

Product: **Diagnostic Ultrasound 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 15223-1：2016	Symbols for use in the labeling of medical devices
EN60601-1:2006/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
EN60601-2-37:2008/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 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices