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-6900
Supplementary information:	Included are following transducers: 35C20EA, 35C50EA, 65EC10EA, 65C15EA, 65EL60EA, 75L38EA, 75L53EA, 75L60EA, 75LT38EA, and following needle-guided brackets: NGB-001, NGB-002, NGB-003, NGB-004, NGB-005, NGB-007, NGB-009, NGB-010, NGB-012,and Mobile trolley: UMT-100，and AC mobile power: DA-88.
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: 2009-03-16

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-V10.0

Applied Standards List

Product: Digital Ultrasonic Diagnostic Imaging System

Model: DP-4900,DP-4800,DP-6900,DP-6800

Standards Applied:

EN ISO14971:2012	Medical devices – Application of risk management to medical devices
EN1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1：2012	Symbols for use in the labelling of medical devices
EN ISO10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
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 - Part1: General Requirements for Safety - 2. Collateral Standard - Electromagnetic compatibility - Requirements and tests
EN60601-1-6: 2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN60601-2-37:2008	Medical electrical equipment Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
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