Declaration of Conformity V1.0

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:	DC-70/DC-70T/ DC-70 Pro /DC-70 Exp/DC-70S
Supplementary information:	Included are following transducers: C5-2E, C11-3E, C7-3E, L12-3E, L14-6NE, L14-6WE, V11-3E, V11-3WE, V11-3BE, P4-2E, P7-3E, D6-2E, DE10-3E, CW5s and following needle-guided brackets: NGB-004, NGB-007, NGB-011, NGB-015, NGB-018, NGB-019, NGB-020, NGB-021, TY-JD-02
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:	2014-8-22
Place, Date of Issue:	Shenzhen, 2014-8-22
Signature:	
Name of Authorized Signatory:	Mr. Tan Chuanbin
Position Held in Company:	Manager, Technical Regulation Department

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Date: 2019.
Reason: Mc
Location: M

Applied Standards List

Product: **Diagnostic Ultrasound System**

Model: DC-70/DC-70T/ DC-70 Pro /DC-70 Exp/DC-70S

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 15223-1：2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirements
EN 60601-1: 2006/AC:2010	Medical Electrical Equipment - Part 1: General Requirements for Safety
EN 60601-1-2: 2007/AC:2010	Medical Electrical Equipment – Part 1-2: General Requirements for Safety -: 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 safety 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 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.