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:	M6/M6 Exp/M6 Pro/M6T/M6s/M55/M58/M5 Exp
Supplementary information:	Included are following transducers: C5-2s, 3C5s, 6C2s, C11-3s, C6-2Gs,7L4s,L7-3s,7L5s,L12-4s, L14-6s, L14-6Ns, 7LT4s,L16-4Hs, P4-2s, 2P2s, P7-3s, P12-4s,V10-4s, V10-4Bs, 6CV1s, 6LB7s, 4CD4s, D7-2s,CW2s, CW5s, P7-3Ts, DE11-3s and following needle-guided brackets: NGB-004, NGB-005, NGB-006,NGB-007,NGB-009, NGB-010, NGB-011, NGB-015, NGB-016, NGB-018, NGB-024, NGB-027
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:	2016. 7. 28
Place, Date of Issue:	Shenzhen, 2016. 7. 28
Signature:	
Name of Authorized Signatory:	Mr. Tan Chuanbin
Position Held in Company:	Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: **Diagnostic Ultrasound System**

Model: M6/M6 Exp/M6 Pro/M6T/M6s/M55/M58/M5 Exp

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
EN60601-1:2006/AC:2010	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