Declaration of Conformity V2.0

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:	Electrocardiograph (Including Accessories)
Model:	BeneHeart R12、BeneHeart R12A
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

Place, Date of Issue:	Shenzhen, 2015.3.20
Signature:	.....
Name of Authorized Signatory:	Mr. Tan Chuanbin
Position Held in Company:	Manager, Technical Regulation

Applied Standards List

Product:	**Electrocardiograph**
Model:	**BeneHeart R12、BeneHeart R12A**

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
EN ISO 15223-1: 2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 10993-1: 2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 60601-1:2006/A1:2013	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 basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2006+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-25:2011	Medical electrical equipment -- Part 2-25: Particular requirements for the safety of electrocardiographs
EN 62304: 2006/AC:2008	Medical device software - Software lifecycle processes
IEC 62366:2007+A1:2014	Medical devices - Application of usability engineering to medical devices