

Declaration of Conformity



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: Ila (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.

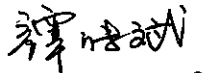
Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany.

Notified Body No. : 0123

Start of CE-Marking:

Place, Date of Issue: Shenzhen,

Signature:


2014.1.8

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 of 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 ISO 10993-1: 2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 60601-1: 1990+A1:1993+A2:1995	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
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
EN 60601-1-4: 1996+A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
EN 60601-1-6: 2007/AC:2010	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -collateral standard: usability
EN 60601-2-25:1995+A1:1999	Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs
EN 60601-2-51: 2003	Medical electrical equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
EN 62366:2008	Medical devices -- Application of usability engineering to medical devices
EN 62304:2006 /AC:2008	Medical device software -- Software life cycle processes
ANSI/AAMI EC11: 1991/(R)2007	Diagnostic electrocardiographic devices