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
Start of CE-Marking:	

Place, Date of Issue: Shenzhen, 2014.1.8

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2024.06.13 17:16:12 EEST
Reason: MoldSign Signature
Location: Moldova

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