

# 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:** Defibrillator/Monitor (Including accessories and Vehicle Mount kit)

**Model:** BeneHeart D1

**Classification:** IIb (According to Rule 9 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, 2013.7.31

**Signature:** 

**Name of Authorized Signatory:** Mr. Tan Chuanbin

**Position Held in Company:** Manager, Technical Regulation

## Applied Standards List

**Product:** Automated External Defibrillator

**Model:** BeneHeart D1

### 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: 1990+A1:1993+A2:1995	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
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: 2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8 : 2007/AC:2010	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-2-4: 2003	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators

**EN 60601-2-27: 2006/AC:2006** Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

**EN 60601-2-49: 2001** Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

**ANSI/AAMI EC13: 2002/(R)2007** Cardiac monitors, heart rate meters, and alarms

**ANSI/AAMI DF80: 2003** Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)

**EN 62366: 2008** Medical devices - Application of usability engineering to medical devices

**EN 62304: 2006/AC:2008** Medical device software - Software life-cycle processes



## 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:** Automated External Defibrillator (Including Accessories)

**Model:** BeneHeart D1

**Conformity Assessment Route:** R&TTE Annex III

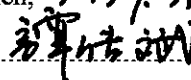
**We herewith declare that the above mentioned products meet the provisions of the Council Directive 1995/5/EC R&TTE Device. All supporting documentations are retained under the premises of the manufacturer.**

### Standards Applied:

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> EN 300 328 V1.7.1    | <input checked="" type="checkbox"/> EN 60601-1-2: 2007/AC:2010       |
| <input checked="" type="checkbox"/> EN 301 489-17 V2.1.1 | <input checked="" type="checkbox"/> EN 60601-1: 1990+A1:1993+A2:1995 |
| <input checked="" type="checkbox"/> EN 301 489-1 V1.8.1  | <input checked="" type="checkbox"/> EN 62311:2008                    |

### Start of CE-Marking:

**Place, Date of Issue:** Shenzhen, 2013.7.31

**Signature:** 

**Name of Authorized Signatory:** Mr. Tan Chuanbin

**Position Held in Company:** Manager, Technical Regulation