



## 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 D3

**Classification:** II b ( 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 for 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:** 2010-12-10

**Place, Date of Issue:** Shenzhen, 2011-09-30

**Signature:**

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

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

## Applied Standards List

**Product:** Defibrillator/Monitor

**Model:** BeneHeart D3

### Applied Standards:

|                                             |                                                                                                                                                                                                                                                           |
|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>EN ISO 14971: 2007</b>                   | Medical devices - Application of risk management to medical devices                                                                                                                                                                                       |
| <b>EN 1041: 2008</b>                        | Information supplied by the manufacturer with medical devices                                                                                                                                                                                             |
| <b>EN 980: 2008</b>                         | Graphical symbols for use in the labeling of medical devices                                                                                                                                                                                              |
| <b>IEC/TR 60878: 2003</b>                   | Graphical symbols for electrical equipment in medical practice                                                                                                                                                                                            |
| <b>ISO 15223:<br/>2000+A1:2002+A2:2004</b>  | Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied                                                                                                                                                    |
| <b>ISO 1000: 1992+A1:1998</b>               | SI units and recommendations for the use of their multiples and of certain other units                                                                                                                                                                    |
| <b>EN ISO 10993-1: 2009</b>                 | Biological evaluation of medical devices - Part 1: Evaluation and testing                                                                                                                                                                                 |
| <b>EN 60601-1:<br/>1990+A1:1993+A2:1995</b> | Medical electrical equipment - Part 1: General requirements for safety                                                                                                                                                                                    |
| <b>EN 60601-1-1: 2001</b>                   | Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems                                                                                                        |
| <b>EN 60601-1-2: 2007</b>                   | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests                                                                    |
| <b>EN 60601-1-4:<br/>1996+A1:1999</b>       | Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems                                                                                                                   |
| <b>EN 60601-1-6: 2007</b>                   | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability                                                                                                                 |
| <b>EN 60601-1-8: 2007</b>                   | 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 |

Attachment of Declaration of Conformity: Applied Standards List – V3.0

|                             |                                                                                                                                                                 |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>EN 60601-2-4: 2003</b>   | Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators                                                       |
| <b>EN 60601-2-27: 2006</b>  | Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment |
| <b>EN 60601-2-49: 2001</b>  | Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment                                  |
| <b>ANSI/AAMI EC13: 2002</b> | Cardiac monitors, heart rate meters, and alarms                                                                                                                 |
| <b>EN ISO 9919: 2009</b>    | Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use               |
| <b>EN 62304: 2006</b>       | Medical device software - Software lifecycle processes                                                                                                          |
| <b>EN 62366: 2008</b>       | Medical devices - Application of usability engineering to medical devices                                                                                       |
| <b>ANSI/AAMI DF80: 2003</b> | Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)         |
| <b>EN 1789: 2007</b>        | Medical Vehicles and Their Equipment - Road Ambulances                                                                                                          |