

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.

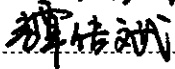
Standards Applied:

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, 2023.7.31

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

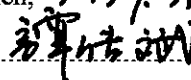
We herewith declare that the above mentioned products meet the provisions of the Council Directive 1995/5/EC R&TTE Device. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

- | | |
|--|--|
| ☒ EN 300 328 V1.7.1 | ☒ EN 60601-1-2: 2007/AC:2010 |
| ☒ EN 301 489-17 V2.1.1 | ☒ EN 60601-1: 1990+A1:1993+A2:1995 |
| ☒ EN 301 489-1 V1.8.1 | ☒ 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