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:	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

Digitally signed by Prodan Sv
Date: 202[illegible]07.05 16:15:39 EE
Reason: MoldSign Signature
Location: Moldova

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

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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