Declaration of Conformity – V3.0

CE 0123

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

Digitally signed by Prodan Sveatoslav
Date: 2020.03.05 11:53:27 EET
Reason: MoldSign Signature
Location: Moldova

Applied Standards List

Product: **Defibrillator/Monitor**

Model: **BeneHeart D3**

Applied Standards:

EN ISO 14971: 2007	Medical devices - Application of risk management to medical devices
EN 1041: 2008	Information supplied by the manufacturer with medical devices
EN 980: 2008	Graphical symbols for use in the labeling of medical devices
IEC/TR 60878: 2003	Graphical symbols for electrical equipment in medical practice
ISO 15223: 2000+A1:2002+A2:2004	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
ISO 1000: 1992+A1:1998	SI units and recommendations for the use of their multiples and of certain other units
EN ISO 10993-1: 2009	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 60601-1-1: 2001	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-2: 2007	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	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8: 2007	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	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	Cardiac monitors, heart rate meters, and alarms
EN ISO 9919: 2009	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
EN 62304: 2006	Medical device software - Software lifecycle processes
EN 62366: 2008	Medical devices - Application of usability engineering to medical devices
ANSI/AAMI DF80: 2003	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators)
EN 1789: 2007	Medical Vehicles and Their Equipment - Road Ambulances