Declaration of Conformity V9.0

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 D2/BeneHeart D3
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

Start of CE-Marking: 2010-12-10

Place, Date of Issue: Shenzhen, 2017.9.30

Signature: .....

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2022.10.21 16:33:46 EEST
Reason: MoldSign Signature
Location: Moldova

Attachment of Declaration of Conformity: Applied Standards List-V8.0

Applied Standards List

Product: Defibrillator/Monitor

Model: BeneHeart D2/BeneHeart D3

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 devices
ISO 15223-1:2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
EN ISO 10993-1: 2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 60601-1:2006/A1:2013	Medical electrical equipment--Part 1:General requirements for basic safety and essential performance
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
IEC 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8: 2012	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
IEC 60601-2-4: 2010	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
IEC 60601-2-27: 2011	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

ISO 80601-2-30: 2013	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
ISO 81060-2: 2013	Non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type
IEC 60601-2-49: 2011	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
ISO 80601-2-61:2011	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 1789: 2007+A1:2010	Medical Vehicles and Their Equipment - Road Ambulances
EN 62366-1: 2015	Medical devices - Application of usability engineering to medical devices
EN 62304: 2006	Medical device software - Software lifecycle processes
ISO 80601-2-55:2011	Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors