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: Automated External Defibrillator (Including Accessories)

Model: BeneHeart C1、BeneHeart C1A、BeneHeart C2、BeneHeart C2A、BeneHeart S1、BeneHeart S1A 、BeneHeart S2 、 BeneHeart S2A

Classification: IIb （According to Rule 9 of MDD Annex IX）

Conformity Assessment Route: MDD Annex Ⅱ excluding (4)

GMDN code: 48047

We 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. This declaration of conformity is issued under the sole responsibility 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: **2019-08-02**

Place, Date of Issue: Shenzhen, 2019.8.2

Signature: .....

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: **Automated External Defibrillator**

Model: BeneHeart C1、BeneHeart C1A、BeneHeart C2、BeneHeart C2A、BeneHeart S1、BeneHeart S1A、BeneHeart S2、BeneHeart S2A

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
ISO 15223-1: 2016	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: 2006/A1:2013	Medical electrical equipment - Part 1: General requirements for safety
EN 60601-1-2: 2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366: 2015	Medical devices - Application of usability engineering to medical devices
EN 60601-2-4:2011	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
IEC 60601-1-12:2015	Medical Electrical Equipment -- Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment
EN 1789: 2007+A2:2014	Medical Vehicles and Their Equipment - Road Ambulance
IEC 60601-1-11-2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and

	essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 62304:2014	Medical device software - Software life-cycle processes