Declaration of Conformity V1.0

Declaration of Conformity

CE 2797

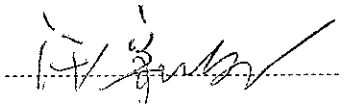
Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Manufacturer SRN:	CN-MF-000014156
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Automated external defibrillator
Model:	BeneHeart C1/BeneHeart C1A/BeneHeart C2/BeneHeart C2A/BeneHeart S1/BeneHeart S1A/BeneHeart S2/BeneHeart S2A/BeneHeart C1 Fully Automatic/BeneHeart C1A Fully Automatic/BeneHeart C2 Fully Automatic/BeneHeart C2A Fully Automatic/BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic
Basic UDI-DI:	69449040AB010000423E
Classification:	III（According to Rule 22 of MDR Annex VIII）
CND code:	Z120305
Conformity Assessment Route:	Annex IX
Intended Purpose:	The Automated external defibrillator is intended for semi-automated external defibrillation and automated external defibrillation.

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:	/
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Notified Body No.	2797
Identification of the Certificate:	MDR 781235
Start of CE-Marking:	2019-08-02

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2024.7.26

Signature: 

Name of Authorized Signatory: Wang Xinbing

Position Held in Company: Deputy director, 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/BeneHeart C1 Fully Automatic/BeneHeart C1A Fully Automatic/BeneHeart C2 Fully Automatic/BeneHeart C2A Fully Automatic/BeneHeart S1 Fully Automatic/BeneHeart S1A Fully Automatic/BeneHeart S2 Fully Automatic/BeneHeart S2A Fully Automatic**

Standards Applied:

EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 20417:2021	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2021	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
IEC 60601-1:2005+A1:2012+A2:2020	Medical electrical equipment--Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance-- Collateral standard: Electromagnetic compatibility--Requirements and tests
IEC 60601-1-6:2010+A1:2013+A2:2020	Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance--collateral standard: usability
IEC 60601-2-4:2010+A1:2018	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
IEC 62366-1:2015+A1:2020	Medical devices – Part 1： Application of usability engineering to medical devices
EN 1789:2020	Medical Vehicles and Their Equipment - Road Ambulances
EN 13718-1:2014+A1:2020	Medical vehicles and their equipment-Air ambulances-Part 1: Requirements for medical devices used in air ambulances

IEC 60601-1-10:2007+A1:2013+A2:2020	Medical electrical equipment Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers
IEC 60601-1-11:2015+A1:2020	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 60601-1-12:2014/AMD1:2020	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
IEC 60086-4:2019	Primary batteries – Part 4: Safety of lithium batteries
EN 62304:2006/A1:2015	Medical device software - Software lifecycle processes