Declaration of Conformity V1.0

CE 0123

Declaration of Conformity

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:	Electrocardiograph
Model:	BeneHeart R900\BeneHeart R90\BeneHeart R700\BeneHeart R70\BeneHeart R300\BeneHeart R30
Basic UDI-DI:	69449040AB010000573T
Classification:	IIa （According to Rule 10 of MDR Annex VIII）
Conformity Assessment Route:	Annex IX excluding CHAPTER II
CND code:	Z120503
Intended Purpose:	The equipment is intended for clinical electrocardiographic diagnosis and study.

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:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	**G10 044751 0176**
Start of CE-Marking:	**2024.08.28**

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,2024.08.28

Signature: .....

Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

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

Applied Standards List

Product: Electrocardiograph

Model: BeneHeart R900\BeneHeart R90\BeneHeart R700\BeneHeart R70\BeneHeart R300\BeneHeart R30

Standards Applied:

EN ISO 14971:2019 A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
IEC 60601-1 A2 2020	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+AMD1:2020	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+AMD1:2013+AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 62304: 2015	Medical device software - Software lifecycle processes
IEC 62366-1:2015+AMD1:2020	Medical devices – Application of usability engineering to medical devices