Declaration of Conformity V3.0

CE 0123

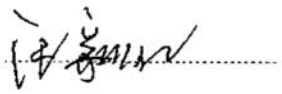
Declaration of Conformity

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Manufacturer SRN:	CN-MF-000014156
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) EiffestraBe 80, 20537 Hamburg, Germany
Product:	Electrocardiograph (Including Accessories)
Model:	BeneHeart R12/ BeneHeart R12A/ BeneHeart R12B/BeneHeart R3/BeneHeart R3A/BeneHeart R3B
Basic UDI-DI:	69449040AB010000563R
Classification:	Ha （According to Rule 10 of MDR Annex VIII）
Conformity Assessment Route:	Annex IX excluding CHAPTER II
CND code:	Z120503
Intended Purpose:	It 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 RidlerstraBe 65 80339 MUnchen, Germany.
Notified Body No. :	0123
Identification of the Certificate:	G10 044751 0176 Rev. 04
Start of CE-Marking:	2014-07-17

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,2024.11.26
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Deputy Director, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V3.0

Applied Standards List

Product: Electrocardiograph

Model: BeneHeart R12/ BeneHeart R12A/ BeneHeart R12B/BeneHeart R3/BeneHeart R3A/BeneHeart R3B

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
ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 60601-1:2005/AMD2:2020	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 disturbances - Requirements and tests
EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes