

Declaration of Conformity V2.0

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)
Eiffestraße 80
20537 Hamburg, Germany

Product: Defibrillator/Monitor

Model: BeneHeart D30/BeneHeart D20/BeneHeart
D20A/BeneHeart D20C/BeneHeart D60/BeneHeart D50/
BeneHeart D50A/BeneHeart D50C/BeneHeart DX/
BeneHeart DM

Basic UDI-DI: 69449040AB010000102Z

Classification: III (According to Rule 22 of MDR Annex VIII)

CND code: Z120305

Conformity Assessment Route: Annex IX

Intended Purpose: The Defibrillator/Monitor is intended for external
defibrillation, internal defibrillation, synchronized
cardioversion and semi-automated external defibrillation. It
can also be used for non-invasive external pacing, CPR
Feedback as well as ECG, Resp, SpO2, PR, NIBP, CO2, IBP
and Temp monitoring.
The intended purpose of BeneHeart D30/BeneHeart
D20/BeneHeart D20A/BeneHeart D20C does not include
IBP and Temp monitoring.

We declare that the products mentioned above 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 757840, MDR757846

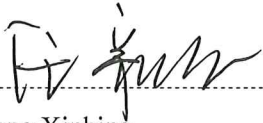
Start of CE-Marking: 2022.11.22

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, 2022.12.28

Signature:



Name of Authorized Signatory:

Wang Xinbing

Position Held in Company:

Deputy director, Technical Regulation

Applied Standards List

Product: Defibrillator/Monitor

Model: BeneHeart D30/BeneHeart D20/BeneHeart D20A/BeneHeart D20C/BeneHeart D60/BeneHeart D50/ BeneHeart D50A/BeneHeart D50C/BeneHeart DX/ BeneHeart DM

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
EN ISO 15223-1:2021	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
EN 60601-1:2006+A1:2013/IEC 60601 1: 2005 +A1:2012	Medical electrical equipment--Part 1: General requirements for basic safety and essential performance
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+A2:2021	Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance--collateral standard: usability
IEC 60601-1-8:2006/AMD1:2012/AMD2:2020	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
EN 60601-2-4:2011/A1:2019	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN IEC 60601-2-27: 2014	Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN IEC 80601-2-30:2019	Medical electrical equipment - part 2-30: particular requirements for the basic safety and

essential performance of automated non-invasive sphygmomanometers

EN ISO 81060-2:2014	Non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type
EN 60601-2-34:2014	Medical electrical equipment - part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
EN IEC 80601-2-49:2019	Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
EN ISO 81060-2-61:2019	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
EN ISO 80601-2-56:2017/A1:2020	Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN ISO 80601-2-55:2018	Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 62304:2006/A1:2015	Medical device software - Software lifecycle processes
EN 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 ISO 17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
EN 60601-1-12:2015+A1:2020	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
EN 60601-1-10:2008+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

Declaration of Conformity V2.0

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

UK-Representative: Mindray UK Ltd.
Mindray House, Kingfisher Way, Hinchingsbrooke Business
Park, Huntingdon, UK, PE29 6FN

Product: Defibrillator/Monitor

Model: BeneHeart D30/BeneHeart D20/BeneHeart D20A/BeneHeart
D20C/BeneHeart D60/BeneHeart D50/ BeneHeart
D50A/BeneHeart D50C/BeneHeart DX/ BeneHeart DM

Classification: IIb(According to rule 9)

Conformity Assessment Route: Annex II excluding (4)

GMDN code: 17882

We declare that the above mentioned products meet the provisions of the UK Medical Devices Regulations 2002. 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: BSI Assurance UK Ltd
Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5
8PP

Notified Body No. 0086

UK certificate No.: UKCA 768496

Start of UK-Marking: 2022.12.19

Place, Date of Issue: Shenzhen, 2022.12.28

Signature: 

Name of Authorized Signatory: Wang Xinbing

Position Held in Company: Deputy director, Technical Regulation

Applied Standards List

Product: Defibrillator/Monitor

Model: BeneHeart D30/BeneHeart D20/BeneHeart D20A/BeneHeart D20C/BeneHeart D60/BeneHeart D50/ BeneHeart D50A/BeneHeart D50C/BeneHeart DX/ BeneHeart DM

Standards Applied:

BS EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
BS EN ISO 20417: 2021	Medical devices-Information supplied by the manufacturer with medical devices
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BS EN 60601-1-6:2010+A2:2021	Medical electrical equipment-part 1-6: general requirements for basic safety and essential performance--collateral standard: usability
BS EN 60601-1-8:2007+A2:2021	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
BS EN 60601-2-4:2011+A1:2019	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
BS EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
BS EN 60601-2-27:2014	Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
BS EN IEC 80601-2-30:2019	Medical electrical equipment - part 2-30: particular requirements for the basic safety and

essential performance of automated non-invasive sphygmomanometers

BS EN ISO 81060-2:2014	Non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type
BS EN 60601-2-34:2014	Medical electrical equipment - part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
BS EN IEC 80601-2-49:2019	Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
BS EN ISO 80601-2-61:2019	Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
BS EN ISO 80601-2-56:2017+A1:2020	Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
BS EN ISO 80601-2-55:2018	Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
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BS EN 62366-1:2015+A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
BS EN 1789:2020	Medical Vehicles and Their Equipment - Road Ambulances
BS ISO 17664-2:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices.
BS EN 60601-1-12:2015+A1:2020	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
BS EN 60601-1-10:2008+A2:2021	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

Declaration of Conformity V2.0



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EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
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D50A/BeneHeart D50C/BeneHeart DX/ BeneHeart DM

We herewith declare that the above mentioned products meet the provisions of the Council
Directive 2011/65/EU, amended by Directive 2015/863/EU. All supporting documentations
are retained under the premises of the manufacturer.

Standards Applied:
EN IEC 63000: 2018

Place, Date of Issue:

Shenzhen, 2022.12.28

Signature:

Name of Authorized Wang Xinbing

Signatory:

Position Held in Company: Deputy director, Technical Regulation

Declaration of Conformity V1.0

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

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Defibrillator/Monitor

Model: BeneHeart D30/BeneHeart D20/BeneHeart D20A/BeneHeart
D20C/BeneHeart D60/BeneHeart D50/ BeneHeart D50A/BeneHeart
D50C/BeneHeart DX/ BeneHeart DM

We herewith declare that the above mentioned products meet the provisions of the Council Directive 2014/53/EU concerning radio equipment. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:

<input checked="" type="checkbox"/> EN 60601-1:2006/A1:2013	<input checked="" type="checkbox"/> EN 60601-1-2: 2015
<input checked="" type="checkbox"/> EN 62311:2008	<input checked="" type="checkbox"/> ETSI EN 301 489-1 V2.2.3
<input checked="" type="checkbox"/> ETSI EN 301 489-3 V2.2.0	<input checked="" type="checkbox"/> ETSI EN 301 489-17 V3.1.1
<input checked="" type="checkbox"/> ETSI EN301 489-19V2.1.1	<input checked="" type="checkbox"/> ETSI EN301 489-52V1.1.0
<input checked="" type="checkbox"/> ETSI EN301 908-1 V13.1.1	<input checked="" type="checkbox"/> ETSI EN 301 908-2 V13.1.1
<input checked="" type="checkbox"/> ETSI EN 301 908-13 V13.1.1	<input checked="" type="checkbox"/> EN301 908-25 V15.1.1_15.0.2
<input checked="" type="checkbox"/> ETSI EN 301 893 V2.1.1	<input checked="" type="checkbox"/> ETSI EN301 511 V12.5.1
<input checked="" type="checkbox"/> EN 300 330V2.1.1	<input checked="" type="checkbox"/> ETSI EN303 413 V1.1.1
<input checked="" type="checkbox"/> ETSI EN 300 328 V2.2.2	/

Place, Date of Issue: Shenzhen, 2023.1.11

Signature:

Name of Authorized Signatory: Wang Xinbing

Position Held in Company: Deputy director, Technical Regulation