Declaration of Conformity V2.0

# Declaration of Conformity

CE 2797

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| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>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)<br>Eiffestraße 80<br>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.<br>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.**

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| **References to CS:** | / |
| **Notified Body:** | BSI Group The Netherlands B.V.<br>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** |

Digitally signed by Cernolev Andrei
Date: 2026.06.01 17:52:57 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

**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:**

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| 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 |

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| | 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

UK CA 0086

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| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China |
| **UK-Representative:** | Mindray UK Ltd.<br>Mindray House, Kingfisher Way, Hinchingbrooke 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.

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| **Notified Body:** | BSI Assurance UK Ltd<br>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:**

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|---|---|
| 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 |
| BS 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 |
| 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 |

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| | 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 |
| BS EN 62304:2006/A1:2015 | Medical device software - Software lifecycle processes |
| 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

CE

# Declaration of Conformity

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|---|---|
| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80<br>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 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 Signatory:** Wang Xinbing

**Position Held in Company:** Deputy director, Technical Regulation

**Declaration of Conformity V1.0**

# Declaration of Conformity

CE

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| **Manufacturer:** | Shenzhen Mindray Bio-Medical Electronics Co., Ltd.<br>Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,<br>Nanshan, Shenzhen, 518057, P. R. China |
| **EC-Representative:** | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestraße 80<br>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:**

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

**Place, Date of Issue:** Shenzhen, 2023.1.1

**Signature:**

**Name of Authorized Signatory:** Wang Xinbing

**Position Held in Company:** Deputy director, Technical Regulation