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
EC-Representative SRN:	DE-AR-000000001
Product:	Patient monitor
Model:	BeneVision N22/BeneVision N22 OR/BeneVision N22 ICU/BeneVision N19/BeneVision N19 OR/BeneVision N19 ICU/ BeneVision M22/BeneVision M22C/BeneVision M19/BeneVision M19C
Basic UDI-DI:	69449040AB0100002238
Classification:	IIb （According to Rule 10 of MDR Annex VIII）
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	33586
CND code:	Z120302
Intended Purpose:	The patient monitor is intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters.

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:	2016-06-24

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, 2023.7.11
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: Patient Monitor

Model: BeneVision N22/BeneVision N22 OR/BeneVision N22 ICU/BeneVision N19/BeneVision N19 OR/BeneVision N19 ICU/ BeneVision M22/BeneVision M22C/BeneVision M19/BeneVision M19C

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, labelling and information to be supplied — Part 1: General requirements
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization Third Edition
EN 60601-1:2006+A1:2013+A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	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/A1:2015/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007/A1:2013/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
EN 60601-2-10:2015+A1:2016	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN IEC 80601-2-26:2020	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
EN 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 60601-2-34:2014	Medical electrical equipment Part 2-34: Particular requirements for the basic safety and 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 80601-2-55:2018	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
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 80601-2-61:2019	Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 81060-2: 2013	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN 62304: 2015	Medical device software - Software lifecycle processes
EN 62366-1:2015+A1:2020	Medical devices – Application of usability engineering to medical devices