Declaration of Conformity-V3.0

Declaration of Conformity

CE 0123

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:	Patient Monitor (Including Accessories)
Model:	BeneVision N1
Classification:	Ⅱb （According to Rule 10 of MDD Annex Ⅸ）
Conformity Assessment Route:	MDD Annex Ⅱ excluding (4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany
Notified Body No. :	0123
Start of CE-Marking:	**2017-10-25**
Place, Date of Issue:	Shenzhen, 2018.12.29
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2022.10.03 19:18:47 EEST
Reason: MoldSign Signature
Location: Moldova

Product:	**Patient Monitor (Including Accessories)**
Model:	BeneVision N1

Applied Standards:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
ISO 15223-1-2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 10993-1:2009/AC:2010	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 and skin sensitization
EN 60601-1: 2006 /A1:2013	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
IEC 60601-1-6:2013	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-1-8:2012	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

IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30:2013	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-34:2011	Medical electrical equipment - Part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
IEC 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-55:2011	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56:2009	Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011	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 validation of automated measurement type
IEC 62366-1:2015	Medical devices Part 1: Application of usability engineering to

	medical devices
EN 62304:2015	Medical device software - Software life cycle processes
IEC 62133:2012+C:2013	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
EN 1789:2014	Medical vehicles and their equipment - Road ambulances
EN 13718-1:2008	Medical vehicles and their equipment-Air ambulances-Part 1: Requirements for medical devices used in air ambulances
MIL STD 461F (Chapter RE101)	Department of defense interface standard requirements for the control of electromagnetic interference characteristics of subsystems and equipment
MIL-STD-810G (Category 13, Category 14, Category 20, Category 24)	Environmental Engineering Considerations and Laboratory Tests
IEC 60601-1-12:2014	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 intended for use in the emergency medical services environment