

Declaration of Conformity-VI.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:

Patient Monitor (Including Accessories)

Model:

BeneVision N17 , BeneVision N15 , BeneVision N12,
BeneVision N12C

Classification:

IIb (According to Rule 10 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding (4)

We herewith declare 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:

2016.12.27

Place, Date of Issue:

Shenzhen

2016.12.27

Signature:

Signature of Authorized Signatory

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Product:

Patient Monitor

Model:

**BeneVision N17 , BeneVision N15 , BeneVision
N12, BeneVision N12C**

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 15223-1:2012

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

ISO 10993-10:2010

Biological evaluation of medical devices - Part 10: Tests
for irritation and and skin sensitization

EN60601-1: 2006 /A1:2013

Medical electrical equipment - Part 1: General
requirements for basic safety and essential performance

EN60601-1-2: 2007/AC:2010

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 60601-2-10:2012

Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

IEC 60601-2-25:2011

Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

IEC 60601-2-26:2012

Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

IEC 60601-2-27:2011

Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

EN 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 62304:2006/AC:2008	Medical device software - Software life cycle processes