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: Patient Monitor (Including Accessories)

Model: N17 BeneVision Z15 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:

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

Notified Body: TÜV SÜD Product Service GmbH

Ridlerstraße 65

80339 München, Germany

Notified Body No.: 012:

Start of CE-Marking: 7016.12. 2

Place, Date of Issue: Shenzhen 7016.12.7

We say

Signature:

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

for in vitro cytotoxicity

Biological

evaluation of medical devices - Part 5:

Tests

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

Medical electrical equipment -- Part 1-2: General

EN60601-1-2: 2007/AC:2010

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

JEC 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
IEC 60601-2-34:2011	sphygmomanometers  Medical electrical equipment - Part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring
IEC 60601-2-49:2011	strical equipment - Part 2-49: for the basic safety and

Medical electrical equipment Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors  Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement  Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment  Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type  Medical devices Part 1: Application of usability engineering to medical devices  Medical device software - Software life cycle processes
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