Declaration of Conformity

Declaration of Conformity V9.0

CE 0123

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:	BeneView T9 \ BeneView T8 \ BeneView T6 \ BeneView T5 \ BeneView T5 OR \ BeneView T9 OR
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 concerning 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: 2006-11-30

Place, Date of Issue: Shenzhen, 2015.8.4

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Digitally signed by Pro
Date: 2021.05.19 15:0
Reason: MoldSign Sig
Location: Moldova

Attachment of Declaration of Conformity: Applied Standards List-V9.0

Applied Standards List

Product:	**Patient Monitor**
Model:	**BeneView T9, BeneView T8, BeneView T6, BeneView T5, BeneView T5 OR, BeneView T9 OR**

Standards Applied:

EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 1041: 2008	Information supplied by the manufacturer with medical devices
EN ISO 15223: 2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC/TR 60878: 2003	Graphical symbols for electrical equipment in medical practice
EN ISO 10993-1: 2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
IEC 60601-1: 2005 +A1：2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2007/AC:2010	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6: 2010+A1：2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8: 2006+A1：2012	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

EN 60601-2-10:2012	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN 60601-2-26:2012	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
EN 60601-2-27: 2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN 60601-2-30: 2009	Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometerst
EN 60601-2-34:2011	Medical electrical equipment Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
EN 60601-2-49: 2011	Medical electrical equipment -- Part 2-49: Particular requirements for the safety 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
EN 62304: 2006/AC:2008	Medical device software - Software lifecycle processes
EN 62366: 2008	Medical devices - Application of usability engineering to medical devices

Declaration of Conformity

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:	BeneView T9 \ BeneView T8 \ BeneView T6 \ BeneView T5 \ BeneView T5 OR \ BeneView T9 OR
Conformity Assessment Route:	R&TTE Annex III

We herewith declare that the above mentioned products meet the provisions of the Council Directive 1995/5/EC R&TTE Device. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

- ☒EN 300 328 V1.8.1
- ☒EN 301 489-17 V2.2.1
- ☒EN 301 489-1 V1.9.2
- ☒EN 60601-1-2: 2007/AC:2010
- ☒ EN 301 893 V1.7.1
- ☒EN 62311:2008

Start of CE-Marking: 2015. 12. 11

Place, Date of Issue: Shenzhen, 2015.12.11

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Declaration of Conformity

Declaration of Conformity V2.0

CE 0123

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:	BeneView T9 \ BeneView T8 \ BeneView T6 \ BeneView T5 \ BeneView T5 OR \ BeneView T9 OR

We herewith declare that the above mentioned products meet the provisions of the Council Directive 2011/65/EU. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

EN 50581:2012.

Start of CE-Marking: 2014-07-18

Place, Date of Issue: Shenzhen, 2015.8.4

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation