Declaration of Conformity

Declaration of Conformity-V1.0

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 Monitors (Including Accessories)

Model: **uMEC6、uMEC7、uMEC10、uMEC12**

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

Digitally signed by Prodan Sveatoslav
Date: 2021.07.05 17:09:34 EEST
Reason: MoldSign Signature
Location: Moldova

Start of CE-Marking: **2016-3-31**

Place, Date of Issue: Shenzhen 2016.3.31

Signature: _____

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Product:	**Patient Monitors**
Model:	**uMEC6、uMEC7、uMEC10、uMEC12**
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
EN60601-1: 2006 /AC:2010	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
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN 60601-1-8:2007/AC:2010	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 60601-2-27:2006/AC:2006	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
EN 60601-2-30:2000	Medical electrical equipment -- Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
EN 60601-2-34:2000	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
EN 60601-2-49:2001	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 62366:2008	Medical devices - Application of usability engineering to medical devices

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

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Product: Patient Monitors (Including Accessories)

Model: **uMEC6、uMEC7、uMEC10、uMEC12**

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: 2016-3-31

Place, Date of Issue: Shenzhen 2016.3.31

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation