Declaration of Conformity

Declaration of Conformity-V3.0

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: Central Monitoring System（contains CentralStation, ViewStation, WorkStation, CMS Viewer, Mobile Viewer）

Model: BeneVision

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: 2015-05-08

Place, Date of Issue: Shenzhen, 2017.8.31

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Product:	**Central Monitoring System**
Model:	**BeneVision**

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 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN 60601-1-8:2006+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 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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20537 Hamburg, Germany

Product: Central Monitoring System（contains CentralStation, ViewStation, WorkStation, CMS Viewer, Mobile Viewer）

Model: BeneVision

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: 2015-05-08

Place, Date of Issue: Shenzhen, 2017.8.31

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation