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: Ventilator (Including Accessories)
Model: **SynoVent E5**
Classification: II b （According to Rule 9 of MDD Annex IX）
Conformity Assessment Route: MDD Annex II excluding (4)

We herewith declare under our sole responsibility 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: **2011-09-09**

Place, Date of Issue: Shenzhen, 2018.7.17

Signature:

Name of Authorized Signatory : Mr. Wang Xinbing
Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product: **Ventilator**

Model: **SynoVent E5**

Applied Standards:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN1041: 2008	Information supplied by the manufacturer with medical devices
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
IEC 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for safety - 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
ISO 80601-2-12:2011	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 80601-2-55:2011	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN EN 62304:2006/AC:2008	Medical device software - Software life cycle processes.
IEC 62366:2007+A1:2014	Medical devices - Application of usability engineering to medical devices

EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements