Declaration of Conformity-V0.1

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: **SV300**
Classification: Ⅱb （According to Rule 11 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: **2014-11-28**

Place, Date of Issue: Shenzhen, 2014.11.28

Signature:

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Digitally signed by Pradan Svetlana
Date: 2019.06.10 16:10:34 EEST
Reason: MoldSign Signature
Location: Moldova

Applied Standards List

Product:	Ventilator
Model:	**SV300**

Applied Standards:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 62304:2006	Medical device software - Software life cycle processes.
EN60601-1: 2006	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN60601-1-2: 2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-8:2007	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 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN1041: 2008	Information supplied by the manufacturer with medical devices
EN ISO 80601-2-12:2011	Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-55:2011	Medical electrical equipment. Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 12342:1998+A1:2009	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN ISO 5359:2008+A1:2011	Low-pressure hose assemblies for use with medical gases
EN ISO 5356-1:2004	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 15001:2011	Anaesthetic and respiratory equipment - Compatibility with oxygen
EN ISO 80601-2-61:2011	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment