Declaration of Conformity-V2.0



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: SV600/SV650/SV800/SV850

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

Signature:

Start of CE-Marking: 2017-9-20

Place, Date of Issue: Shenzhen, 2018. 1.15

Name of Authorized Signatory: Mr. Wangxinbing

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product:	Ventilator
Model:	SV600/SV650/SV800/SV850

Applied Standards:

EN 160 14071 2012	Medical devices Application of risk management to medical
EN ISO 14971:2012	devices
IEC 62304:2006	Medical device software - Software lifecycle processes
EN 1041: 2008	Information supplied by the manufacturer of medical devices
EN ISO15223-1:2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
IEC60601- 1:2005+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC60601-1- 6:2010+A1:2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366:2007+A1:2014	Medical devices - Application of usability engineering to medical devices
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 ISO 10993- 1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN ISO 80601-2- 12:2011	Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
ISO 11195:1995	Gas mixers for medical use Stand-alone gas mixers
EN 13544- 2:2002+A1:2009	Respiratory therapy equipment - Part 2: Tubing and connectors
EN ISO 5359:2014	Low-pressure hose assemblies for use with medical gases
EN ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

EN ISO 80601-2-55:2011	Medical electrical equipment. Particular requirements for the
	basic safety and essential performance of respiratory gas
	monitors
EN ISO 80601-2-61:2011	Medical electrical equipment - Part 2-61: Particular
	requirements for basic safety and essential performance of
	pulse oximeter equipment
EN ISO 18082:2014	Anaesthetic and respiratory equipment - Dimensions of non-
	interchangeable screw-threaded (NIST) low-pressure
	connectors for medical gases