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: **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

Start of CE-Marking: **2017-9-20**

Place, Date of Issue: Shenzhen, 2018.6.15

Signature:

Name of Authorized Signatory: Mr. Wangxinbing

Position Held in Company: Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2023.02.24 16:31:06 EET
Reason: MoldSign Signature
Location: Moldova

Applied Standards List

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

Applied Standards:

EN ISO 14971:2012	Medical devices -- Application of risk management to medical 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