

Declaration of Conformity-V2.0



## 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:**

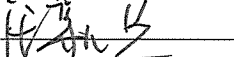
List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

**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

## Applied Standards List

|                 |                         |
|-----------------|-------------------------|
| <b>Product:</b> | Ventilator              |
| <b>Model:</b>   | 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                                                                                                                                                                    |

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|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| 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 |