



## 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:** Anaesthetic Vaporizer

**Model:** V60

**Classification:** II b (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:** 2011-09-26

**Place, Date of Issue:** Shenzhen, 2015. 5. 4

**Signature:** \_\_\_\_\_

**Name of Authorized Signatory:** Mr. Tan Chuanbin

**Position Held in Company:** Manager, Technical Regulation

## Applied Standards List

**Product:** Anaesthetic Vaporizer

**Model:** V60

### Applied Standards:

<b>EN ISO 14971:2012</b>	Medical devices – Application of risk management to medical devices
<b>EN1041: 2008</b>	Information supplied by the manufacturer with medical devices
<b>EN980: 2008</b>	Graphical symbols for use in the labeling of medical devices
<b>EN ISO 5360:2012</b>	Anaesthetic vaporizers -- Agent-specific filling systems
<b>EN 62366:2008</b>	Medical devices - Application of usability engineering to medical devices
<b>EN 60601-1:2006</b>	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
<b>ISO 80601-2-13: 2011</b>	Medical electrical equipment --Part 2-13:Particular requirements for basic safety and essential performance of an anaesthetic workstation
<b>EN ISO15223-1: 2012</b>	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
<b>EN 60601-1-6:2010</b>	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability