



## Declaration of Conformity

**Manufacturer:** Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Mindray Building, Keji 12th Road South, High-tech Industrial  
Park, Nanshan, Shenzhen, 518057, P. R. China

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80  
20537 Hamburg, Germany

**Product:** Anesthesia System (Including Accessories)

**Model:** WATO EX-55 Pro、WATO EX-65 Pro

**Classification:** IIb (According to Rule 11 of MDD Annex IX)

**Conformity Assessment Route:** MDD Annex IIexcluding (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:** 2016-7-13

**Place, Date of Issue:** Shenzhen, 2020.12.31

**Signature:** 

**Name of Authorized Signatory:** Mr. Wang Xinbing

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

## Applied Standards List

**Product:** Anesthesia System

**Model:** WATO EX-55 Pro、 WATO EX-65 Pro

**Applied Standards:**

<b>EN ISO 14971:2019</b>	Medical devices – Application of risk management to medical devices
<b>EN 60601-1: 2006/A1:2013</b>	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
<b>EN 60601-1-2:2015</b>	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
<b>EN ISO 80601-2-13:2012/A2:2019</b>	Medical electrical equipment Part 2-13:Particular requirements for basic and essential performance of an anesthetic workstation
<b>EN ISO 80601-2-55:2018</b>	Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
<b>IEC 60601-2-10:2016</b>	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
<b>EN 60601-2-26:2015</b>	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
<b>EN ISO 10079-3:2014</b>	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
<b>EN ISO 5359:2014/A1:2017</b>	Low-pressure hose assemblies for use with medical gases

<b>EN ISO 5356-1:2015</b>	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
<b>EN ISO 5360:2016</b>	Anaesthetic vaporizers - Agent-specific filling systems
<b>EN 62366-1:2015</b>	Medical devices - Application of usability engineering to medical devices
<b>EN 62304:2006/A1:2015</b>	Medical device software - Software life cycle processes.
<b>EN 60601-1-6:2010/A1:2015</b>	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
<b>EN 60601-1-8:2007/A1:2017</b>	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
<b>EN ISO 10993-1:2009/AC:2010</b>	Biological evaluation of medical devices - Part 1: Evaluation and testing
<b>EN 1041:2008</b>	Information supplied by the manufacturer with medical devices
<b>EN ISO 15223-1:2016</b>	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements



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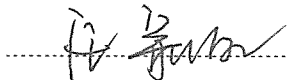
We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU. All supporting documentations are retained under the premises of the manufacturer.

**Standards Applied:**

EN 50581:2012.

**Start of CE-Marking:** 2016-7-13

**Place, Date of Issue:** Shenzhen, 2020/12/31

**Signature:** 

**Name of Authorized Signatory:** Mr. Wang Xinbing

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