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: Anesthesia Machine (Including Accessories)

Model: **WATO EX-65**

Classification: Ⅱb （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

Digitally signed by Prodan Sveatoslav
Date: 2022.09.15 10:31:03 EEST
Reason: MoldSign Signature
Location: Moldova

Notified Body No. : 0123

Start of CE-Marking: **2008-4-30**

Place, Date of Issue: Shenzhen, 2016.5.5

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product:	**Anesthesia Machine**
Model:	**WATO EX-65**
Applied Standards:	
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN60601-1: 2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2007/AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO 80601-2-13:2011	Medical electrical equipment Part 2-13:Particular requirements for basic and essential performance of an anesthetic workstation
ISO 80601-2-55:2011	Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 60601-2-26:2003	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
EN ISO 10079-3:2009	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
EN ISO 5359:2008+A1:2011	Low-pressure hose assemblies for use with medical gases
EN ISO 5356-1:2004	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5360:-2012	Anaesthetic vaporizers - Agent-specific filling systems

EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006	Medical device software - Software life cycle processes.
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
EN 60601-1-8:2007/AC:2010	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
ENISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN 980:2008	Symbols for use in the labelling of medical devices
ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements