Declaration of Conformity-V4.0

CE 0123

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

Digitally signed by Prodan Sveatoslav
Date: 2023.02.24 16:31:50 EET
Reason: MoldSign Signature
Location: Moldova

Applied Standards List

Product: **Anesthesia System**

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

Applied Standards:

EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 60601-1: 2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN ISO 80601-2-13:2012/A2:2019	Medical electrical equipment Part 2-13:Particular requirements for basic and essential performance of an anesthetic workstation
EN ISO 80601-2-55:2018	Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
IEC 60601-2-10:2016	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN 60601-2-26:2015	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
EN ISO 10079-3:2014	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
EN ISO 5359:2014/A1:2017	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 5360:2016	Anaesthetic vaporizers - Agent-specific filling systems
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life cycle processes.
EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
EN 60601-1-8:2007/A1:2017	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
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

Declaration of Conformity V3.0

CE

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

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