

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: 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: 2008-4-30

Place, Date of Issue: Shenzhen, 2016. ±.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

Medical electrical equipment -- Part 1-2: General requirements

EN 60601-1-2: 2007/AC:2010

for basic safety and essential performance - Collateral standard:

Electromagnetic compatibility - Requirements and tests

Medical electrical equipment

Part 2-13:Particular

ISO 80601-2-13:2011

requirements for basic and essential performance of an

anesthetic workstation

Medical electrical equipment - Part 2-55: Particular

ISO 80601-2-55:2011

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

Anaesthetic and respiratory equipment - Conical connectors -

EN ISO 5356-1:2004

Part 1: Cones and sockets

EN ISO 5360:-2012

Anaesthetic vaporizers - Agent-specific filling systems

Medical devices - Application of usability engineering to
medical devices
Medical device software - Software life cycle processes.
Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
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
Biological evaluation of medical devices - Part 1: Evaluation and testing
Information supplied by the manufacturer with medical devices
Symbols for use in the labelling of medical devices
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements