Declaration of Conformity-V.02

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 Pro**

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: 2019.06.25 15:03:17 EEST
Reason: MoldSign Signature
Location: Moldova

Notified Body No. : 0123

Start of CE-Marking: **2012-04-20**

Place, Date of Issue: Shenzhen, 2014. 11. 18

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 Pro**
Applied Standards:	
EN ISO 14971:2007	Medical devices – Application of risk management to medical devices
EN1041: 2008	Information supplied by the manufacturer with medical devices
EN980: 2008	Graphical symbols for use in the labeling of medical devices
IEC 60878: 2003	Graphical symbols for electrical equipment in medical practice
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN60601-1: 1990+A1:1993 +A2:1995	Medical Electrical Equipment, Part 1: General Requirements for Safety
EN60601-1-1: 2001	Medical Electrical Equipment- Part 1-1: General Requirements for Safety - Collateral Standard: Safety requirements for medical electrical systems
EN60601-1-2: 2007/AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-4:1996/A1:1999	Medical electrical equipment Part 1-4: General requirements for Safety - Collateral Standard: Programmable electrical medical systems
EN 60601-1-6:2007	Medical electrical equipment - Part 1-6: General

	requirements for safety - Collateral standard: Usability
EN 60601-1-8:2007	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 21647:2009	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN 60601-2-13:2006/A1:2007	Medical electrical equipment Part2.requirements for the safety of anesthetic workstations
EN ISO 8835-2:2009	Inhalational anaesthesia systems - Part 2: Anaesthetic breathing system for adults
EN ISO 8835-3:2009	Inhalational anaesthesia systems - Part 3: Anaesthetic gas scavenging systems - Transfer and receiving systems
EN ISO 8835-4:2009	Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices
EN ISO 8835-5:2009	Inhalational anaesthesia systems - Part 5: Anaesthesia ventilators
EN 60601-2-26:2003	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006	Medical device software - Software life cycle processes.