Declaration of Conformity-V.05

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-35**
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

Notified Body No. : 0123

Start of CE-Marking: **2010-09-21**

Place, Date of Issue: Shenzhen, 2011-10-18

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product: **Anesthesia Machine**

Model: **WATO EX-35**

Applied Standards:

EN ISO 14971:2007	Medical devices – Application of risk management to medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices
EN 980: 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: 2001+A1:2006	Medical Electrical Equipment Part 1-2: General Requirements for Safety - 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 basic safety and essential performance - 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 60601-2-13:2006/A1:2007	Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems
EN ISO 21647:2009	Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN ISO 8835-2:2009	Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems

Attachment of Declaration of Conformity：Applied Standards List-V.05

EN ISO 8835-3:2009	Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging 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 ISO 15001:2004	Anaesthetic and respiratory equipment - Compatibility with oxygen
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 62304:2006	Medical device software - Software life cycle processes.