Declaration of Conformity-V1.0

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: Ventilator (Including Accessories)

Model: **NB300/NB350/NB380**

Classification: Ⅱb （According to Rule 9 of MDD Annex Ⅸ）

Conformity Assessment Route: MDD Annex Ⅱ excluding (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

Digitally signed by Prodan Sveatoslav
Date: 2021.07.05 15:57:23 EEST
Reason: MoldSign Signature
Location: Moldova

Notified Body No. : 0123

Start of CE-Marking: **2020-3-26**

Place, Date of Issue: Shenzhen, 2020.3.26

Signature:

Name of Authorized Signatory: Mr. Wangxinbing

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product:	Ventilator
Model:	**NB300/NB350/NB380**

Applied Standards:

EN ISO 14971:2012	Medical devices -- Application of risk management to medical devices
EN 62304:2006/A1:2015	Medical device software - Software lifecycle processes
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1: 2016	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
EN 60601-1: 2006/ A1: 2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-6:2010/ A1: 2015	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1:2015	Medic device Part 1: Application of usability engineering to medical devices
IEC 60601-1-8:2006/A1:2012	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 60601-1-2:2015	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN ISO 5359-2014	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
ISO 80601-2-55:2011	Medical electrical equipment. Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-61:2011	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

ISO 11195:2018	Gas mixers for medical use -- Stand-alone gas mixers
EN ISO 18082:2014/A1:2017	Anaesthetic and respiratory equipment - Dimensions of noninterchangeable screw-threaded (NIST) low-pressure connectors for medical gases
EN ISO 9170-1：2008	Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum

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Product: Ventilator (Including Accessories)

Model: NB300/NB350/NB380

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.

Place, Date of Issue: Shenzhen, 2020.3.26

Signature:

Name of Authorized Signatory: Mr. Wangxinbing

Position Held in Company: Manager, Technical Regulation