Appendix A Declaration of Conformity- (Control No.: CV6001-01-V3.2)

Declaration of Conformity-V3.2

CE 0123

Declaration of Conformity

Manufacturer: RESVENT Medical Technology Co., Ltd.
Room-602, Building B&C, Gaoxinqi Industrial Park,
Liuxian NO.1 Road, XingDong community, Bao'an, 518100
ShenZhen,PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Ventilator (Including accessories)

Model: **RS300,RS200,RS100,RS NEO, RV200,RV100,RV NEO**

GMDN Code **42411**

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 and the Annexs. All supporting documentations are retained under the premises of the manufacturer. Resvent is exclusively responsible for the DoC.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

EC Certificate NO.: G1 096632 0011 Rev.01

Valid until: 2024-05-26

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany

Notified Body No. : 0123

Start of CE-Marking: **January 16, 2018**

Place, Date of Issue: Shenzhen

Signature: Manxin Wang 2020.12.04

Name of Authorized Signatory: Mr. Wang Yalin

Position Held in Company: Management Representative

Applied Standards List

Product	**Ventilator (Including accessories)**
Model	**RS300,RS200,RS100,RS NEO, RV200,RV100,RV NEO**

Applied Standards:

EN ISO 14971:2012 **ISO 14971:2019**	Medical devices - Application of risk management to medical devices
EN 60601-1:2006/A1:2013 **IEC 60601-1:2005/A1:2012**	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015 **IEC 60601-1-2:2014**	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO 80601-2-12:2011	Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators
ISO 80601-2-74:2017	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems
ISO 5356-1-2015	Anaesthetic and respiratory equipment - conical connectors: part 1: cones and sockets.
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007+A1:2013 **IEC 60601-1-8:2007/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
IEC 62304:2006+A1:2015	Medical device software - Software life-cycle processes
IEC 62366-1 Edition 1.0 2015-02	Medical devices - Application of usability engineering to medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016 **ISO 15223-1:2016, Corrected version 2017-03**	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements.
EN ISO 10993-1:2009/AC:2010 **ISO 10993-1:2009**	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 80601-2-55:2011	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
IEC 60529-2013	Degrees of protection provided by enclosures (IP Code)
IEC 62133-2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ISO 5359 Fourth edition 2014-10-01/A1:2017	Anaesthetic and respiratory equipment-Low-pressure hose assemblies for use with medical gases
ISO 5367 Fifth edition 2014-10-15	Anaesthetic and respiratory equipment -- Breathing sets and connectors
ISTA 2A-2011	Packaged-Products 150lb(68 kg) or Less
ISO 3744: Third edition 2010-10-01	Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure —Engineering methods for an essentially free field over a reflecting plane