Appendix A Declaration of Conformity(Control No.: HR0601-01-V2.0)

Declaration of Conformity

CE 0123

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:	PAP System (Including Accessories)
Model:	iBreeze 20C、iBreeze 20C Pro、iBreeze 20A、iBreeze 20A Pro、iBreeze 25S、iBreeze 25A、iBreeze 25A Pro、iBreeze 25ST、iBreeze 25STA、iBreeze 25STA Pro、iBreeze 30ST、iBreeze 30STA、iBreeze 30STA Pro、iBreeze Tech、iBreeze F20C Pro、iBreeze F20A Pro、iBreeze F20A
UMDNS Code	11001
Classification:	IIa（According to Rule 11 of MDD Annex IX）
Conformity Assessment Route:	MDD Annex IIexcluding (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 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.00
Valid until	2021-11-15
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany
Notified Body No. :	0123
Start of CE-Marking:	March 31, 2017
Place, Date of Issue:	Shenzhen
Signature:	Tang Hao 2020, 03, 10
Name of Authorized Signatory:	Mr. Tang Hao
Position Held in Company:	Regulatory Manager

Applied Standards List

Product	**PAP System**
Model	iBreeze 20C、iBreeze 20C Pro、iBreeze 20A、iBreeze 20A Pro、iBreeze 25S、iBreeze 25A、iBreeze 25A Pro、iBreeze 25ST、iBreeze 25STA、iBreeze 25STA Pro、iBreeze 30ST、iBreeze 30STA、iBreeze 30STA Pro、iBreeze Tech、iBreeze F20C Pro、iBreeze F20A Pro、iBreeze F20A

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
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
ISO80601-2-70:2015	Medical electrical equipment-Part 2-70: Particular requirements for basic safety and essential performance of Sleep apnoea breathing therapy equipment
EN ISO 17510-2:2009	Sleep apnoea breathing therapy - Part 2: Masks and application accessories
EN ISO 8185:2009	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
IEC 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 62304-2015	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices

EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

Директору УП «Центр экспертиз
и испытаний в здравоохранении»

Заявление

Прошу заключить договор на проведение первичной экспертизы документов на следующую медицинскую технику:

- Система для двухфазной вентиляции легких с положительным давлением в дыхательных путях iBreeze BPAP System: 25S, 25A, 25A Pro, 25ST, 25STA, 25STA Pro, 30ST, 30STA, 30STA Pro, Tech;

- Система для вентиляции легких с положительным давлением в дыхательных путях iBreeze CPAP System: 20C, 20C Pro, 20A, 20A Pro;

производства Resvent Medical Technology Co., Ltd. (Китай).

Валюта платежа: Евро.

С уважением,

Член правления «AldarInvest» OU
(на основании доверенности от 33.04.2020)

Aliaksandr Kryuda

19.11.2020

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