Declaration of Conformity to Council Directive 93/42 EEC

Concerning Medical Devices

For the following products:

Product Name: Oxygen Concentrator

Model Designation: KSW-5,KSOC-10

We, the manufacturer, herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June, 1993, All supporting documentation is retained at the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex II certificate issued by the notified body.

The manufacturer is exclusively responsible for the DOC.

Harmonized standards:

Refer to the Appendix A

Conformity Assessment Route: According to 93/42/EEC, Annex II, excluding section 4.

Classification (93/42/EEC, Annex IX): Rule 11, Class IIa.

The following representative in Europe is responsible for making this declaration:

Company Name: Shanghai International Holding Corp. GmbH (Europe)
Company Address: Eiffestrasse 80, 20537 Hamburg Germany

The following manufacturer is responsible for making this declaration:

Manufacturer Name: Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

Address: NO.8, Shengchang West Road, Danyang Economy Development Zone, Jiangsu Province,

212300 China.

Notified Body:

SGS Belgium NV
Noorderlaan 87
BE-2030 Antwerpen
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(Legal Signature)	(Position/title)	(Place)	(Date)
Wu Jujia	General Manager	Konsung	2020.8.3

Appendix A: Harmonized standards

Standard	Description
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1:2006+A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN ISO 80601-2-69:2014	Medical electrical equipment — Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
EN 60601-1-8:2007/A11:2017	Medical electrical equipment General requrements for basic safety and essentical performance-Collateral standard:General requirements,tests and guidance for alarm systems in medical electrical equipement and medical electrical systems.
EN ISO 10993-10:2013	Biological evaluation of medical devices-Part 10: Tests for irritation and skin
EN 15986:2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates
EN ISO 8359:2009/A1:2012	Oxygen concentrators for medical use - Safety requirements
EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications.
EN ISO 18562-2:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
EN ISO 18562-3:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Technical Corrigendum 1
EN ISO 10993-5 :2009	Biological evaluation of medical devices - Part 5: Tests for in
EN ISO 15001:2011	Anaesthetic and respiratory equipment - Compatibility with oxygen