Owgels 5L Oxygen Concentrator

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A GERMAN RESPIRATORY THERAPIST SINCE 1963

OXYGEN CONCENTRATOR

Product manual \ Model: OZ-5-01TW0

Germany Ougels Group Share GmbH
Schumannstr. 27 60325 Frankfurt am Main Deutschland

DON'T OPERATE THIS DEVICE WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL. IF YOU ARE UNABLE TO UNDERSTAND THE WARNINGS AND INSTRUCTIONS, CONTACT YOUR EQUIPMENT PROVIDER BEFORE ATTEMPTING TO USE THIS EQUIPMENT; OTHERWISE, INJURY OR DAMAGE MAY RESULT.

Smoking while using oxygen is the number one cause of fire, injury, and death. You must follow these safety warnings.

Do not allow smoking, candles, or open flames within the same room of the device or the oxygen-carrying accessories.

Smoking while wearing an oxygen cannula may result in facial burns or likely death.

Removing the cannula and placing it on surfaces such as bedding, sofas, or other cushion material will cause a flash fire when exposed to a cigarette, heat source, or flame.

If you smoke, you must follow these 3 life-saving steps: turn off the oxygen concentrator, take off the cannula and leave the room where this device is located.

"No Smoking-Oxygen in Use" signs must be prominently displayed in the room, or where the oxygen concentrator is in use. Patients and their caregivers must be informed about the dangers of smoking in the presence of, or while using medical oxygen.

CONTENTS

1 Intended Use and Instructions

Intended Use

The OZ-5-01TW0 Oxygen Concentrator is designed to provide supplementary oxygen to patients who have been diagnosed with oxygen therapy. It delivers a high concentration of oxygen and is used with a cannula to channel oxygen from the concentrator to the patient. This device may be used at home or Institutions.

This device is expected to work for a period of 5 years. For a longer use, please consult your Equipment Provider and physician.

WARNING Availability of an alternate source of oxygen is recommended in case of power outage, or mechanical failure. Consult your Equipment Provider for type of back-up system recommended.

WARNING This device is not intended to be life sustaining and life supporting. Geriatric, pediatric, or any other patient unable to communicate discomfort while using this oxygen concentrator may require additional monitoring. Patients with hearing and/or sight impairments may need assistance with monitoring the alarms. If you feel discomfort, or are experiencing a medical emergency, seek medical assistance immediately.

WARNING Do not use oil, grease, or petroleum-based product on or near the OZ-5-01TW0 Oxygen Concentrator.

WARNING Do not use extension cords with this device or connect too many plugs into the same electrical outlet. This can result in an overload to the electrical panel causing the breaker/fuse to activate.

WARNING Use only voltage specified on back panel label.

WARNING Care should be taken to prevent the device from getting wet or allowing water to enter the device. This can cause the device to malfunction or shut down, and cause an increased risk for electric shock or burns.

WARNING No modification of this device is allowed.

WARNING This device should not be used adjacent to or stacked with other equipment.

CAUTION It is very important to follow the prescribed oxygen flow. Do not increase or decrease the flow until you first consult your physician.

CAUTION Ensure the device is operated in an upright position.

CAUTION Position the device away from curtains or drapes, hot air or any heating devices Be certain to place the device on a flat surface and make sure all sides are at least 1 foot (30 cm) away from a wall or other obstruction. Do not place the device in a confined area. Choose a dust-and-smoke-free area. Do not operate the unit outdoors. Avoid exposing it to direct sunlight.

CAUTION To prevent a void of the warranty, follow all manufacturer's instructions.

CAUTION The device releases warm air from the bottom of the machine, which can permanently discolor temperature sensitive flooring surfaces. The concentrator should not be used over flooring that is sensitive to hot air.

2 Description of the OZ-5-01TW0 Oxygen Concentrator

Front and Back of Concentrator

Control Panel

Alert/ Alarm Lights

Control Buttons

Display

Display

- Displays information regarding cumulative hours of operation, and time for each therapy set for the patient.

Oxygen Outlet Port

-Provides connection for a cannula.

Flow Setting Knob

-Controls the oxygen flow rate in liters per minute (LPM).

Humidifier Bottle

-Humidifies the oxygen before it reaches the patient.

Flow Meter

-indicates flow rate.

Oxygen Button

-Pressed to start oxygen delivery.

Timer

-Sets the time of each therapy.

Switch

-Starts and stops power supply to this concentrator.

Alert/ Alarm Lights

- Illuminates to alert or alarm the user in case of a condition that may need immediate attention.

Accessories

CAUTION

The accessories listed below are recommended for use with this device. The use of any other accessories which are not specified for use with this device may reduce performance and void manufacturer's warranty.

Humidifier Bottle	1 Piece
Cannula	1 Piece
Filter	1 Piece
Nasal cannula	1 Piece

User Controls

On/Off Button

Get the device powered on or off by turning on/off switch

Oxygen Button

Press once and wait for 1 second to let the device start delivering oxygen; Press again to stop delivery of oxygen.

Timer Button

Use this button to set how long you want to do oxygen therapy each time. By default, there is no limitation of time, and it delivers oxygen without any stop unless you set how long you want to do oxygen therapy. with every press of button time increases by 10 minutes. 5 hours is the limitation you can set and then it goes off automatically.

User Interfaces

Display

This screen displays information regarding timing, total time, and alert or alarm. By default, the words showing the type of alert or alarm are not visible. When there is an error during operation, a color light related to this error will illuminate which will prompt the user for appropriate action to be taken.

Indicator Lights

There are 4 lights in all. When the concentrator is powered on, the rightmost green LED light will be illuminous. When the oxygen purity drops below 82%, the second LED light from the left will turn yellow to cause an alarm to sound. When the outlet pressure is low, the first LED light from the left will turn yellow and an alarm will sound. When there is a power outage, the third LED light from the left will turn red and an alarm will sound.

Flow Meter

Rotate the knob on top of the flow meter to set the flow as prescribed by your phisician or doctor. The black ball inside of the flow meter indicates the flow at which the device delivers oxygen.

3 Operating Instructions

General Instructions

1. Place the concentrator in a well ventilated location.

Air intake and exhaust must have clear access.

WARNING Avoid use of this device in presence of pollutants, smoke, or fumes. Do not use this device in presence of flammable anesthetics, cleaning agents or other chemical vapors.

CAUTION Do not obstruct air intake or exhaust when operating the device. Blockage of air circulation or proximity to a heat source may lead to internal heat buildup and shutdown or damage the concentrator.

2. Ensure both particle filters are in place.

CAUTION Do not operate the device without both particle filters in place. Particles drawn into the system may damage the device.

3. Install the humidifier bottle.

The humidifier bottle includes a cup, and onto it, a cap, with two ports, one connected to the concentrator, and the other, the oxygen outlet port.

By default, the cap screwed onto the cup properly is inserted into position when you receive the concentrator. Before operating this concentrator, please extract it from the concentrator, and screw out the cup from the cap, and fill it with distilled or purified water to a level between the lines marked with “MAX” and “MIN”., and screw the cup with filled water back into the cap, and insert the humidifier bottle as a whole into the concentrator.

CAUTION Make sure the bottle has been screwed tightly before starting the device. Leakage of oxygen may happen if it has not been screwed back tightly.

CAUTION If it is the first time you want to use the bottle, the bottle and the cap should be put into a liquid mixed with 1 part white vinegar and 3 parts water, and get them submersed for 30 minutes. Clean them again with purified water till there is no residue of that liquid.

4. Connect the Power Supply

Connect the AC power output plug to an electrical outlet.

CAUTION Ensure the power supply is in a well ventilated location as it relies on air circulation for heat dissipation. The power supply may become hot during operation. Make sure the power supply cools down before handling.

CAUTION Do not disassemble the power supply. This may lead to component failure and/or safety risk.

CAUTION Do not place anything in the power supply port other than the supplied wall cord. Avoid the use of electrical extension cords with the concentrator. If an extension cord must be used, please consult your Equipment Provider.

5. Connect the nasal cannula tubing to the oxygen outlet port.

The oxygen outlet port is located on the top of the concentrator. Use of a single cannula going with this concentrator is recommended to avoid restriction of oxygen delivery.

CAUTION The cannula before used the first time, should be submersed into a liquid mixed with 1 part white vinegar and 3 parts water for 30 minutes, and get them cleaned with water till there is no residue of this liquid.

6. Power the concentrator on by turning on the switch, and press the “Oxygen” button to start oxygen delivery.

The rightmost light and the display will be illuminated after the concentrator is powered on.

7. Set the concentrator to the flow prescribed by your physician.

Rotate the knob on top of the flow meter to set the flow as prescribed by your phisician or doctor.

8. Position the nasal cannula on your face and breathe through your nose.

Please place the nasal cannula over your ears, and position the two prolongs of the nasal cannula into your nose, and start oxygen therapy.

9. Turn off the concentrator.

After each oxygen therapy, please press the “Oxygen” button to stop oxygen delivery and turn off the switch to power the concentrator off. Remove the cannula , and keep it well for next time use.

4 Cleaning, Care and Maintenance

Cannula Replacement

Your nasal cannula should be replaced on a regular basis. Consult your physician and/or Equipment Provider for replacement information. This cannula is recommended to ensure oxygen delivery.

CAUTION Use of a cannula other than the one with this concentrator may restrict oxygen delivery.

Case Cleaning

You may clean the outside case using a cloth dampened with a mild liquid detergent and water.

WARNING Disconnect the power cord from electric outlet before you clean the device to prevent accidental electric shock and burn hazard. Only your Equipment Provider or a qualified service technician should remove the covers or service the device.

WARNING Do not use cleaning agents other than those specified in this User Manual. Do not use alcohol, isopropyl alcohol, ethylene chloride or petroleum based cleaners on the cases or on the particle filters.

Filter Replace

Filters should be replaced as per the reminder that will show on the display. But keep a watchful eye on the status of the filters. If your local area is not good, the filters should be replaced earlier than the reminder. For more detailed information, please consult your Equipment Provider.

Disposal of Equipment and Accessories

Please dispose off the replaceable parts properly as per the Government disposal norms

5 Troubleshooting

If your concentrator fails to operate properly, consult your Equipment Provider, and refer to the troubleshooting chart on the following pages for probable causes and solutions.

CAUTION Do not attempt any maintenance other than the possible solutions listed below.

Problem	Probable Cause	Solution
Limited oxygen flow at a setting of high flow	Due to leakage from the humidifier bottle	Make sure the air flow is smooth
	Leakage, twisting, or chocking of to the cannula	
overheat	Indoor temperature is too high	Make sure unit is located in a well ventilated space and exhaust vent has not been blocked
	Exhaust vent is blocked	
Fogs appear in the cannula	Water in the humidifier bottle is hot	Fill cold water
	Too much water in the bottle	Make sure water level is between MAX and Min
	Unit is located in a poorly ventilated space, causing a high temperature	Move unit to a well ventilated space
	Unit crashes suddenly when in operation	Stop and start again to eliminate fog
	Folding of tube will cause a unit to crash	Straighten the cannula
	Fan is disabled or runs slowly, causing a high temperature	Consult your Equipment Provider to replace fan, or remove any hindrance next to the fan

Problem	Probable Cause	Solution
Display shows information, but compressor and fan do not operate	Frequent starting and shutting down unit cause a crash	Restart unit after 10 minutes
	Main circuit board malfunctions	Consult your Equipment Provider to replace main circuit board
Continuous beep, sounds and unit does not operate	The output plug is not connected properly	Plug power cord tightly
	The electrical outlet gives no power	Reconnect the output plug to another electrical outlet that works
	The power resetting switch breaks	Press resetting switch
	Main control circuit malfunctions	Consult your Equipment Provider to replace main circuit board
After starting the unit operates, but displays show nothing but messy codes	Display board is not connected to power due to falloff of wires inside	Consult your Equipment Provider to do troubleshooting
	Wires of display board are damaged	
	Display board malfunctions	
Control buttons do not work	No response after buttons are pressed	

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6 Product Specifications

Flow Specifications	1 LPM-5 LPM
Oxygen Concentration	93% (+3%, -3%)
Electrical Requirements	Please see back panel label
Power Consumption	330 Watts
Sound	50 dBa
Dimensions	13.4 in. W×11. 8 in. D×25. 6 in. H (34 cm W×30 cm D×65 cm H)
Weight	41.9 lbs (19 kg)
Environmental Limit Conditions	Operating Conditions: 5℃ to 55 ℃ Storage: -20℃ to 60℃ Relative Humidity: up to 80% RH

Operating out of these operational specifications can limit the concentrator's ability to meet oxygen concentration specification at higher liter flow rates.

Cut along the line

TERMS AND CONDITIONS

1.This warranty is limited to the original purchaser of the unit and is valid for a period of 24 months or 15000 cumulative running hours,depending on whichever comes to the end earlier from the date of the purchase shown overleaf.
2. Any defective part or assembly will be repaired or replaced at the sole discretion and determination of distributor,if the unit has been properly operated and used during the warranty period.
3.Repairs or replacements of parts under warranty will be carried out by the company or by our approved service dealers Only.
4.Normal maintenance items and disposable components like Canula,Humidity Bottle,Filters or Mask accessories etc. are not covered by this warranty. All expenses incurred in Shipping or collecting the unit or its parts,to and from the company/approved service dealer shall be paid by the purchaser.
5.This warranty does not apply to damages caused by customer usage of the product, or if the instrument is tampered with,modified,or if and attempt is made to repair partially/fully by any unauthorized person/party.
6.This warranty will be null and void if the serial number on this product has been altered or removed/or if the purchaser fails to presend the filled warranty card/Manual with which the item was purchased initially.
7.This warranty is null and void if the filters are not replaced on time and the machine is used with dirty choked filters/or water damage to the electronics of machine due to any type of negligence.
8.The customer is responsible for the supply of adequate stabilizer/UPS and input power for the machine.Any damages caused due to improper power supply voids the warranty.
9.Machine should be run in clean environment where the dust is minimal.Machine should be used without the Thermocol or Plastic covering around it so that to allow the air to circulate.Humidity bottle water should be changed daily for prolonged life of the unit.
10.The warranty extended is in lieu of all implied conditions and warranties under the law and is confined to repairs OR replacement of the defective parts only,and does not cover any consequential or resulting in any liability damages or less. Furthermore,this warranty in no case shall extend to payment of any monetary consideration or replacement or return of the product as a whole.

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Post Stamp

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Customer copy

WARRANTY CARD

Product Code :

Serial Number :

Bill Number :_____

Date of Purchase :_____

Dealer Stamp:

Marketed and Manufactured by:

owgels

Company Copy

WARRANTY CARD

Customer Name:_____

Product Code:

Serial Number:

Bill Number:_____

Date of Purchase:_____

Dealer Stamp:

Telephone:_____

E-mail:_____

Cut along the line

July 20, 2020

Guangzhou Life Light Electronic Technology Co., Ltd.
o Iris Fung
Project Manager
SGS-CSTC Standards Technical Services Co., Ltd.
108 Kezhu Road
Scientech Park Guangzhou Economic & Technology
Guangzhou, 510060 Cn

Re: K191875
Trade/Device Name: Owgels Oxygen Concentrator, Model: OZ-5-02TW0
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: March 15, 2020
Received: April 7, 2020

Dear Iris Fung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

EC Certificate Production Quality Assurance System FI20/07009

The management system of

Guangzhoy2LiJe.lJgtit Electronic i8Chrlology <Jo, Ltd.

No. A102, No.1 Kesheng Road,
BaiyunDistrictGuangzhou,510540
P.R. China

has been assessed and certified as meeting the requirements of

Directive93/42/EEC

on Medical Devices, Annex V

For the following products

Owgels Oxygen Concentrator

Products covered arelisted in Attachmen1tof this certificate

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FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Thiscertificate is valid from 11 May 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 11 May 2020
This certificationis based on decision: FI20/07017PO

Authorised by

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Seppo Vahasalo
Notified Body Manager

SGS Fimko Ltd., Notified Body 0598
Takomotie8, FI-00380 Helsin,kFiinland
t +3589 696361 f +3589 692 5474 www.sgs.com

Attachment 1 to SGS Fimko Ltd. EC certificate FI20/07009 Issue 1

Manufacturer	Guangzhou Life Light Electronic Technology Co., Ltd..
Address	No. A102, No.1 Kesheng Road, Baiyun District, Guangzhou, 510540 P.R. China
Activity and Medical Device Product Cateaorv	93/42/EEC Annex V Oxvnen Concentrators

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/tvoe(s)
Owaels Oxvnen Concentrator	.. Ila	OZ-5-01PW0
Owaels Oxvaen Concentrator	Ila	OZ-5-01XW0
Owoels Oxvaen Concentrator	Ila	OZ-5-01OW0
Owaels Oxvnen Concentrator	Ila	OZ-5-01LW0
Owaels Oxvnen Concentrator	Ila	OZ-5-01GW0
Owaels Oxvaen Concentrator	Ila	OZ-5-01NW0
Owaels Oxvnen Concentrator	Ila	OZ-5-01ZW0
Owaels Oxvnen Concentrator …….	Ila	OZ-5-01RW0
Owaels Oxvaen Concentrator: ••. •	Ila	OZ-5-01TW0

DECISION

11 May 2020

FI20/07017P0

Guangzhou Life Light Electronic Technology Co., Ltd.
No. A102, No.1 Kesheng Road,
Baiyun District, Guangzhou, 510540
P.R. China

EC-certification application 18/089-1, dated 02 September 2019 (updated from original 18/089-0, 08 October 2018).

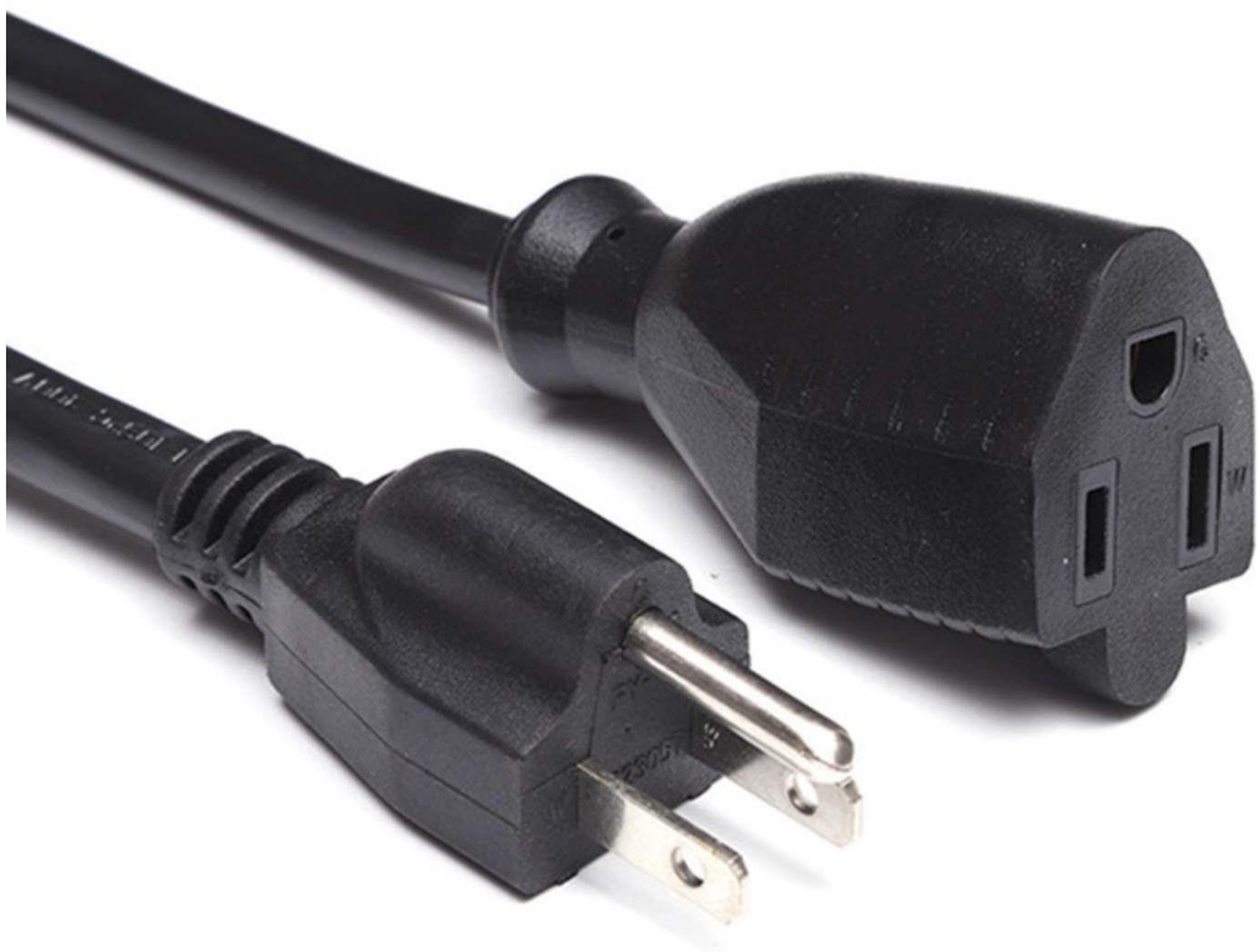
Subject	Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V Section 3.
Manufacturer	Guangzhou Life Light Electronic Technology Co., Ltd. No. A102, No.1 Kesheng Road, Baiyun District, Guangzhou, 510540 P.R. China
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Owgels Oxygen Concentrator	OZ-5-01PVV0	IIa
Owgels Oxygen Concentrator	OZ-5-01XW0	IIa
Owgels Oxygen Concentrator	OZ-5-01OW0	IIa
Owgels Oxygen Concentrator	OZ-5-01LW0	IIa
Owgels Oxygen Concentrator	OZ-5-01GW0	IIa
Ow.gels Oxygen Concentrator	OZ-5-01NW0	IIa
Owgels Oxygen Concentrator	OZ-5-01ZW0	IIa
Owgels Oxygen Concentrator	OZ-5-01RW0	IIa
Owgels Oxygen Concentrator	OZ-5-01TW0	IIa

Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision is based on audit and technical file review report(s) 292881, dated 18 October 2019 The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.
Certificate related to decision	FI20/07009, Issue 1
Attachment to certificate	Attachment 1
Valid until	This decision is valid until 24 May 2024 providing the requirements of the certification are fulfilled.
Date	Helsinki, 11 May 2020

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd, Notified Body 0598

Plug standard



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Medical silicone nasal oxygen tube

Filter

Medical SL oxygen concentrator

Oxygen concentraion and Nebulization

Int elligent **alarmsystem**

SL High flow

German compressor

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