SGS

EC Certificate Production Quality Assurance System FI20/07009

The management system of

Guangzhou Life Light Electronic Technology Co., Ltd.

No. A102, No.1 Kesheng Road, Baiyun District, Guangzhou, 510540 P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex V

For the following products

Owgels Oxygen Concentrator

Products covered are listed in Attachment 1 of this certificate

This certificate 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 certification is based on decision: FI20/07017P0

Authorised by

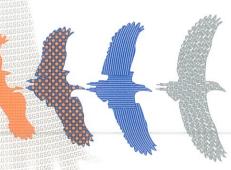
Seppo Vahasalo Notified Body Manager

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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	93/42/EEC Annex V
Device Product Category	Oxygen 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)/type(s)
Owgels Oxygen Concentrator	lla	OZ-5-01PW0
Owgels Oxygen Concentrator	lla	OZ-5-01XW0
Owgels Oxygen Concentrator	lla	OZ-5-01OW0
Owgels Oxygen Concentrator	lla	OZ-5-01LW0
Owgels Oxygen Concentrator	lla	OZ-5-01GW0
Owgels Oxygen Concentrator	lla	OZ-5-01NW0
Owgels Oxygen Concentrator	lla	OZ-5-01ZW0
Owgels Oxygen Concentrator	lla	OZ-5-01RW0
Owgels Oxygen Concentrator	lla	OZ-5-01TW0

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11 May 2020

DECISION

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 6888888888888888888888888888888888888	Model	Class
Owgels Oxygen Concentrator	OZ-5-01PW0	lla
Owgels Oxygen Concentrator	OZ-5-01XW0	lla
Owgels Oxygen Concentrator	OZ-5-01OW0	lla
Owgels Oxygen Concentrator	OZ-5-01LW0	lla
Owgels Oxygen Concentrator	OZ-5-01GW0	lla
Owgels Oxygen Concentrator	OZ-5-01NW0	lla
Owgels Oxygen Concentrator	OZ-5-01ZW0	lla
Owgels Oxygen Concentrator	OZ-5-01RW0	lla
Owgels Oxygen Concentrator	OZ-5-01TW0	lla
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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