

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

### Owgers 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

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

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

<b>Medical Device</b>	<b>Class</b>	<b>Trademark(s) and Model(s)/type(s)</b>
Owgers Oxygen Concentrator	Ila	OZ-5-01PW0
Owgers Oxygen Concentrator	Ila	OZ-5-01XW0
Owgers Oxygen Concentrator	Ila	OZ-5-01OW0
Owgers Oxygen Concentrator	Ila	OZ-5-01LW0
Owgers Oxygen Concentrator	Ila	OZ-5-01GW0
Owgers Oxygen Concentrator	Ila	OZ-5-01NW0
Owgers Oxygen Concentrator	Ila	OZ-5-01ZW0
Owgers Oxygen Concentrator	Ila	OZ-5-01RW0
Owgers Oxygen Concentrator	Ila	OZ-5-01TW0

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No. A102, No.1 Kesheng Road,  
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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
Owgers Oxygen Concentrator	OZ-5-01PW0	Ila
Owgers Oxygen Concentrator	OZ-5-01XW0	Ila
Owgers Oxygen Concentrator	OZ-5-01OW0	Ila
Owgers Oxygen Concentrator	OZ-5-01LW0	Ila
Owgers Oxygen Concentrator	OZ-5-01GW0	Ila
Owgers Oxygen Concentrator	OZ-5-01NW0	Ila
Owgers Oxygen Concentrator	OZ-5-01ZW0	Ila
Owgers Oxygen Concentrator	OZ-5-01RW0	Ila
Owgers Oxygen Concentrator	OZ-5-01TW0	Ila

**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