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营业执照



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(副本)

名称 柯尔(苏州)医疗科技有限公司

类型 有限责任公司

法定代表人 曹大林

经营范围 研发、生产、销售医疗器械；自营和代理各类商品及技术的进出口业务（国家限定企业经营或禁止进出口的商品及技术除外）；消毒剂销售；厨具卫具及日用杂品批发；文具用品零售；体育用品及器材零售；会议及展览服务；电子元器件批发；仪器仪表批发；计算机软硬件及辅助设备零售；针纺织品零售；（依法须经批准的项目，经相关部门批准后方可开展经营活动）



注册资本 15100万元整

成立日期 2018年07月24日

营业期限 2018年07月24日至*****

住所 苏州市高新区科技城玉屏路6号

登记机关



2020年02月10日

医疗器械生产许可证

许可证编号：苏食药监械生产许20190086号

企业名称：柯尔（苏州）医疗科技有限公司

生产地址：苏州市高新区科技城玉屏路6号

法定代表人：曹大林

生产范围：见医疗器械生产产品登记表

企业负责人：曹大林

住所：苏州市高新区科技城玉屏路6号

发证部门：江苏省药品监督管理局

有效期限：至 2024 年 07 月 04 日

发证日期：2019 年 07 月 05 日



医疗器械生产产品登记表

企业名称	柯尔（苏州）医疗科技有限公司			
许可证编号	苏食药监械生产许20190086号			
许可证有效期限	2019-07-05 至 2024-07-04			
生产范围	II类:08-04-医用制氧设备, 08-05-呼吸、麻醉、急救设备辅助装置			
生产产品列表				
序号	产品名称	注册号	登载日期	备注
1	医用制氧机	苏械注准 20192080666	2019-07-05	
2	压缩式雾化器	苏械注准 20192081352	2019-12-24	
<p>发证部门(公章): 江苏省药品监督管理局 2019年12月24日</p> 				

中华人民共和国医疗器械注册证

注册证编号：苏械注准 20192080666

注册人名称	柯尔（苏州）医疗科技有限公司
注册人住所	苏州市高新区科技城玉屏路 6 号
生产地址	苏州市高新区科技城玉屏路 6 号
代理人名称	不适用
代理人住所	不适用
产品名称	医用制氧机
型号、规格	CR-F1、CR-F1W、CR-F3、CR-F3W、CR-F3SW、CR-F5、CR-F5W、 CR-F5SW、CR-H3、CR-H3W、CR-H3SW、CR-H5、CR-H5W、CR-H5SW、 CR-P1、CR-P1W、CR-P3、CR-P3W、CR-P3SW、CR-P5、CR-P5W、 CR-P5SW、CR-Q3、CR-Q3W、CR-Q3SW、CR-Q5、CR-Q5W、CR-Q5SW
结构及组成	医用制氧机由制氧主机、流量控制器、湿化瓶和氧浓度状态指示灯组成。
适用范围	供医疗机构、家庭缺氧患者给氧、水雾化用。
附件	产品技术要求
其他内容	
备注	原《分类目录》产品分类编码：6854。



审批部门：江苏省药品监督管理局

批准日期：2019 年 06 月 24 日

有效期至：2024 年 06 月 23 日

Certificate CN20/42124

The management system of

CARER Medical Technology Co., LTD.

No. 6, Yuping Road, High-Tech Zone,
Suzhou City, Jiangsu Province, 215000, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

**Design and Manufacture of Medical Oxygen Concentrator
and Compression Nebulizer**

This certificate is valid from 20 June 2020 until 19 June 2023
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 29 May 2023

Issue 1. Certified since 20 June 2020

Authorised by



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SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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EC Certificate Full Quality Assurance System: Certificate CN21/968398

The management system of

CARER Medical Technology Co., LTD.

No. 6, Yuping Road, High-Tech Zone,
Suzhou City, Jiangsu Province, 215000, P.R. China
has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

Medical Oxygen Concentrator
Model: CR-F5SW, CR-F3W, CR-P3W, CR-P5W

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 15 April 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 15 April 2021.

Certification is based on reports numbered CN/SZH 10920

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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CARER⁺

New upgrade Intelligent oxygen

P Series Medical Oxygen Concentrator



P3W
New
upgrade



Medical Oxygen Concentrator



CR-P3W

- **Super HD large screen**
Intelligent adjustment of brightness
- **Low noise operation**
Have a quiet time inhaling oxygen
- **Filter replacement**
Intelligent reminder
- **One camera dual use**
Oxygen/Atomization
- **Voice operation prompt**

Power supply AC220V±22V 50Hz±1Hz

Power 300VA

Noise 42dB(A)*

Net weight 14.8kg

Oxygen flow rate 0.5-3L/min

Oxygen concentration 93%±3%

Dimensions 33x34x53cm

Package size 42x40x61cm

*CARER's lab test data may vary from product to product.

CARER Medical Technology Co., Ltd.

Add.: No. 6 Yuping Road, High-tech Zone, Suzhou, Jiangsu, China.

Tel.: +86-512-6680 1111

After-sale service hotline: +86-400 8765 615

Website: www.carertec.com

Production license No.: SSYJXSCX No. 20190086

Registration Certificate No./Technical Specification No.: SXZZ 20192080666

Registrant/Production Dept./After-sales service unit: CARER Medical Technology Co., Ltd.

Domicile/Production address: No. 6 Yuping Road, High-tech Zone, Suzhou, Jiangsu, China.

CARER⁺

New upgrade Intelligent oxygen

P Series Medical Oxygen Concentrator



P5W
New
upgrade



Medical Oxygen Concentrator



CR-P5W

- **Super HD large screen**
Intelligent adjustment of brightness
- **Low noise operation**
Have a quiet time inhaling oxygen
- **Filter replacement**
Intelligent reminder
- **One camera dual use**
Oxygen/Atomization
- **Voice operation prompt**

Power supply AC220V±22V 50Hz±1Hz

Power 450VA

Noise 45dB(A)*

Net weight 16.6kg

Oxygen flow rate 0.5-5L/min

Oxygen concentration 93%±3%

Dimensions 33x34x53cm

Package size 42x40x61cm

*CARER's lab test data may vary from product to product.

CARER Medical Technology Co., Ltd.

Add.: No. 6 Yuping Road, High-tech Zone, Suzhou, Jiangsu, China.

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