



# 医疗器械质量管理体系认证证书

证书编号: 47724MDQ10018R0S

兹证明

**深圳市宏鑫源电子有限公司**

注册地址: 深圳市龙岗区龙岗街道南约社区植物园路 95-1 号 A 栋 501

经营地址: 深圳市龙岗区龙岗街道南约社区植物园路 95-1 号 A 栋 501

建立的医疗器械质量管理体系符合标准  
GB/T 42061-2022/ISO 13485:2016

通过认证范围如下:

资质许可范围内制氧机的生产、销售所涉及的相关管理活动

首次发证日期: 2024 年 08 月 19 日    本次发证日期: 2024 年 08 月 19 日    有效期至: 2027 年 08 月 18 日



签 发

本证书颁发后, 3 年有效期内要至少接受 2 次监督审核, 证书即时有效性可通过网站 ([www.bsicert.com](http://www.bsicert.com)) 查询。

本证书信息可在国家认证认可监督管理委员会官方网站 ([www.cnca.gov.cn](http://www.cnca.gov.cn)) 上查询。

**百胜国际认证 (深圳) 有限公司**

地址: 深圳市龙华区民治街道民新社区鑫茂公寓写字楼 B3008A





# MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:47724MDQ10018R0S

We hereby certify that

**Shenzhen Hongxinyuan Electronics Co., Ltd**

Registered Address:501, Building A, No. 95-1 Botanical Garden Road,  
Nanyue Community, Longgang Street, Longgang District, Shenzhen  
Business Address:501, Building A, No. 95-1 Botanical Garden Road,  
Nanyue Community, Longgang Street, Longgang District, Shenzhen

by reason of its

**Quality Management System of Medical Devices**  
has been awarded this certificate for compliance with the standard  
**GB/T 42061-2022/ISO 13485:2016**

The Quality Management System Applies in the following area:

**Management activities related to the production and sales of  
oxygen concentrators within the scope  
of qualification licensing**

Certified since: Aug.19, 2024

Valid from: Aug.19, 2024

Valid until: Aug.18, 2027



signature by

After this certificate is issued, there should be at least 2 surveillance audits within the 3 year period of validity, the current validity of the certificate can be checked on ([www.bsicert.com](http://www.bsicert.com)).  
The certificate information is available on the official website of the National Certification and Accreditation Administration ([www.cnca.gov.cn](http://www.cnca.gov.cn)).

**Baisheng International Certification Shenzhen Company Limited**

Address: B3008A, Xinmao Apartment Office Building, Minxin Community, Minzhi Street, Longhua District, Shenzhen