



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) 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) 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).
The certificate information is available on the official website of the National Certification and Accreditation Administration (www.cnca.gov.cn).

Baisheng International Certification Shenzhen Company Limited

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