

POSI

CERTIFICATE

## 质量管理体系认证证书

兹证明

厦门华康奥斯医疗器械有限公司

统一社会信用代码：91350205094359224K

注册地址：厦门市海沧区东孚大道2881-13号202室

经营地址：福建省厦门市海沧区东孚大道2881号13#厂房2层西侧202-1、202-2、202-3、202-4

的质量管理体系适用于：

腰部支具（腰部固定器）、下肢支具（髌部固定器、膝部固定器、足部固定器）、踝部支具（踝部固定器）、手部支具（肘部固定器、手指固定器、手臂固定器、腕关节固定器）、肩臂吊带（肩部固定带）、颈托（颈部固定器）的研发、生产和销售；束缚带、锁骨带（背背佳）的研发、生产和销售（仅限出口）；电动轮椅、手动轮椅、拐杖、助行器的销售（仅限出口）

已经通过上海波西认证有限公司根据标准：

GB/T 42061-2022/ISO 13485:2016

审核和注册

本注册要求组织必须按照上述标准保持其质量管理体系，并由POSI进行监督。

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

查询网站：[www.posicert.com](http://www.posicert.com)

该证书信息可在国家认证认可监督管理委员会官方网站<http://cx.cnca.cn>查询。



证书编号：381250323R0M

首次发证日期：2025.10.13

本次发证日期：2025.10.13

有效期：2028.10.12



上海波西认证有限公司

中国（上海）自由贸易试验区世纪大道1500号1402A室 Email: [info@posicert.com](mailto:info@posicert.com)

# POSI CERTIFICATE

This is to certify that the Quality Management System of

## **Xiamen Huakang Orthopedic Co.,Ltd**

Business License Number: 91350205094359224K

Registered Address: Room202, No. 2881-13 Dongfu Avenue, Haicang District,  
Xiamen City, Fujian Province, China

Audit Address: 202-1, 202-2, 202-3, and 202-4, west side of the 2nd floor, Building 13,  
No. 2881 Dongfu Avenue, Haicang District, Xiamen City, Fujian Province, China

applicable to

Research, development, production, and sales of Lumbo-Sacral back brace (lumbar fixators), limb braces (hip fixators, knee fixators, foot fixators), Ankle external brace (ankle fixators), Hand Splint (elbow fixators, finger fixators, arm fixators, wrist joint fixators), Shoulder Arm Sling (shoulder straps), and Cervical Collar (neck fixators); Research and development, production, and sales of Clavicle Splint and Abdominal Binder (back and back preferred) (export only); Sales of Crutch, Walker (fixed walker), Manual wheelchair and Electric wheelchair (export only)

has been assessed and registered by POSI against the provisions of

### **GB/T 42061-2022/ISO 13485:2016**

This registration is subject to the company maintaining a Quality Management System,  
to the above standard, which will be monitored by POSI.

Certified organization shall accept regular surveillance audit, the validity of certificates shall  
be maintained for the positive result of audit.

Please consult the website: [www.posicert.com](http://www.posicert.com)

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



Certificate Registration No: 381250323R0M

Initial issue date: 2025.10.13

Issue date: 2025.10.13

Valid until: 2028.10.12

Shanghai POSI Certification Co., Ltd.

Room 1402A, No.1500, Century Avenue, China (Shanghai) Pilot Free Trade Zone. Email: [info@posicert.com](mailto:info@posicert.com)

