



Orion Registrar, Inc.
Thorough and Fair Auditing

Certificate of Certification

This is to certify the Quality Management System of:

FIH México Industry, S.A. de C.V.

Avenida Cristóbal Colón
No. 20301, Col. Las Aldabas
Chihuahua, Chihuahua C.P. 31170 México

Has been assessed by Orion Registrar and found to be in compliance with the following Quality Standard:

ISO 13485:2016

The Quality Management System is applicable to:

**SMT Manufacturing, Assembly,
and clean room for Medical Devices**

*The Certification period is from
August 31, 2022 to August 23, 2025*

This certification is subject to the company maintaining its system to the required standard, and applicable exceptions, which will be monitored by Orion.

Client ID: 3715

Certificate ID: 1025472




Paul M. Burck, President
September 20, 2022
Date



Registration No. 04723Q10000476

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that:

Futaijing Precision Electronics (Beijing) Co., Ltd.

Registered address: No. 9 JinXiu Street, Beijing Economic & Technology Development Zone, Beijing, P.R.China
Manufacturing address: A01-2-01, 2nd floor, A01, Building 4, No.2 Dize Road, Beijing Economic & Technology Development Zone, Beijing, P.R.China; A01-2-11, 2nd floor, A01, Building 4, No.2 Dize Road, Beijing Economic & Technology Development Zone, Beijing, P.R.China; 3rd floor, A18, Building 4, No.2 Dize Road, Beijing Economic & Technology Development Zone, Beijing, P.R.China

Operates a Quality Management System which complies with the requirements of:

GB/T 42061-2022 idt ISO 13485:2016

For the following scope:

Contract Manufacture of Non-invasive Blood Glucose Meter;
Contract Manufacture of Non-Invasive Hemodynamic Monitor.

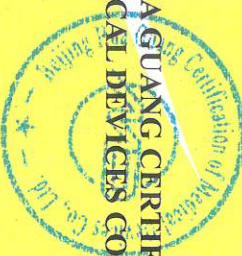
Date of issue: September 27, 2023

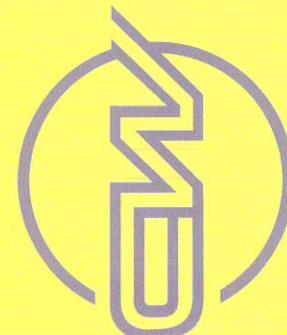
Date of expiry: September 26, 2026

Date of change: October 31, 2024

General manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.





证书编号: 04723Q10000476

医疗器械

质量管理体系认证证书

兹证明

富泰京精密电子(北京)有限公司

(统一社会信用代码: 91110302795103715C)

住 所: 北京市北京经济技术开发区锦绣街 9 号
生产地址: 北京市北京经济技术开发区地泽路 2 号 4 栋 A01 二层 A01-2-01;
北京市北京经济技术开发区地泽路 2 号 4 栋 A01 二层 A01-2-11;
北京市北京经济技术开发区地泽路 2 号 4 栋 A18 三层

质量管理体系符合:

GB/T 42061-2022 idt ISO 13485:2016

体系覆盖:

无创血糖仪、心输出量测量仪的受托生产。

颁证日期: 2023 年 09 月 27 日
有效期至: 2026 年 09 月 26 日
换证日期: 2024 年 10 月 31 日

总经理:

北京国医械华光认证有限公司



富智康精密电子（廊坊）有限公司

统一社会信用代码: 911310007984431765

经营地址: 河北省廊坊市安次区龙河高新技术产业开发区富饶道 18 号

注册地址: 河北省廊坊市安次区龙河高新技术产业开发区富饶道 18 号

的质量管理体系适用于

医疗器械（超声手术刀）用塑胶件的生产和销售

已经 NQA 根据标准

ISO 13485:2016

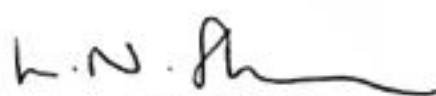
审核和注册

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 NQA 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。

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

SNQCA 官方网站: www.snqa.com.cn



总经理

证书号: 131375

初次发证日期: 2022 年 07 月 29 日

本次发证日期: 2023 年 07 月 17 日

证书有效期至: 2025 年 07 月 29 日



0015

