



**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**

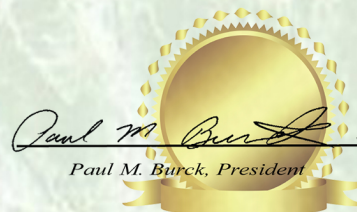
*The Certification period is from*

**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.*

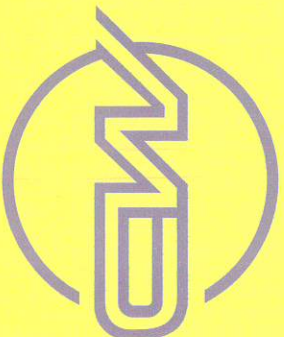
Client ID: 3715

Certificate ID: 1025472



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

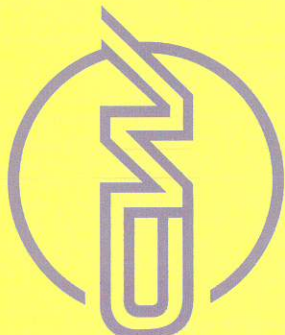
Date of expiry: September 26, 2026

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: 北京市经济技术开发区锦绣街 9 号

生产地址: 北京市经济技术开发区地泽路 2 号 4 栋 A01 二层 A01-2-01;  
北京市经济技术开发区地泽路 2 号 4 栋 A01 二层 A01-2-11;  
北京市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:

李朝晖

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

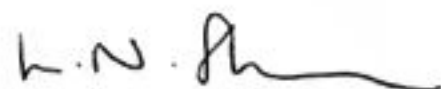
审核和注册

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](http://www.cnca.gov.cn)）上查询

SNQA 查询网站：[www.snqa.com.cn](http://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



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