



英格尔认证

INGEER CERTIFICATION ASSESSMENT SERVICES

MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certification No: 117 23 Q0M 0067 R0S

Suzhou Changqi Plastic Mold Products Co., Ltd.

This is to certify that:

Suzhou Changqi Medical Technology Co., Ltd.

Unified social credit code: 91320585MA1Q61KJ09/91320585MA1XXYDUXT

Registered Address: 2F, Building 5 (Plot 5), No. 90 Zhaoxi Road, Shaxi Town, Taicang City, Jiangsu Province
Building 5, Zone 5, No. 90 Zhaoxi Road, Shaxi Town, Taicang City, Suzhou City, Jiangsu Province

Business Address: 1-2F, Building 5 (Plot 5), No. 90 Zhaoxi Road, Shaxi Town, Taicang City, Jiangsu Province

The established MS conforms to: ISO13485:2016

Scope of approval: R&D, Production and Sales of Disposable Plastic Consumables for In Vitro Diagnostic Reagents

Signed by:



First Certification: 09 May 2023

Expiry Date: 08 May 2026

Shanghai Ingeer Certification Assessment Co., Ltd.

Certification and Accreditation Administration of PRC: CNCA-R-2003-117

Tel: 400-633-9001 / +86 021-51114700

Web: www.icasiso.com

Add: Room 801, HuaDing Mansion, 2368# West Zhongshan Rd., Xuhui District, Shanghai, China, 200235



Focus on icas WeChat platform



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First Surveillance Audit

Second Surveillance Audit

Third Surveillance Audit

The ownership of the certificate belongs to Shanghai Ingeer Certification Assessment Co., Ltd. The information & validation of this certificate can be checked on the CNCA website: WWW.CNCA.GOV.CN and ICAS website, or by calling ICAS's clients services Dept. The certificate is only valid when used together with related permits when appropriate. If the organization can't effectively maintain the above management system, ICAS has the right to withdraw the qualification certificate.



英格尔认证
INGEER CERTIFICATION ASSESSMENT SERVICES

医疗器械质量管理体系认证证书

认证编号: 117 23 Q0M 0067 R0S

兹证明:
苏州长锜塑模制品有限公司
苏州长锜医疗科技有限公司

统一社会信用代码: 91320585MA1Q61KJ09/91320585MA1XXYDUXT

注册地址: 江苏省太仓市沙溪镇昭溪路90号5幢(5#地块) 厂房二层
江苏省苏州市太仓市沙溪镇昭溪路90号5区5幢

经营地址: 江苏省太仓市沙溪镇昭溪路90号5幢(5#地块) 厂房一至二层

建立的管理体系符合: ISO 13485:2016 医疗器械 质量管理体系 用于法规的要求

认证范围: 体外诊断试剂用一次性塑料耗材的研发、生产、销售

核 准:



初次发证: 2023年05月09日

有效期至: 2026年05月08日

上海英格尔认证有限公司

国家认监委批准号: CNCA-R-2003-117

电话: 400-633-9001 / +86 021-51114700

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