



# 医疗器械质量管理体系认证证书

本证书在国家规定的行政许可、资质、强制性产品认证有效期内并应于证书有效期前，按规定执行监督审核并经审核合格的情况下保持有效，本证书可通过以下方式查询：

- 1、扫描证书上的二维码
- 2、本机构网站 <http://www.nsyglobal.com>
- 3、中国国家认监委官方网站 <http://www.cnca.gov.cn>



兹证明

无锡国盛生物工程股份有限公司

统一社会信用代码：913202000502141380

注册地址：江苏省无锡市梁溪区汇太路35号

经营地址：江苏省无锡市梁溪区汇太路35号

医疗器械质量管理体系符合如下标准

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

证书覆盖范围

体外诊断用PCR管、PCR板、酶标板、培养皿、吸头、深孔板、保存管、反应管、反应杯的制造和销售

证书编号：38524MDQ0099R0M

初始发证日期：2024-02-29

证书换发日期：

发证日期：2024-02-29

有效期至：2027-02-28



ISO 13485



证书签发人

### 新标元认证（上海）有限公司

地址：中国（上海）自由贸易试验区金港路211号中新传媒大厦10楼1002-1003室

电话：021-50562313；邮箱：[info@nsyglobal.com](mailto:info@nsyglobal.com)



## Medical devices Quality Management System Certificate

This certificate shall remain valid within the validity period of the administrative license, qualification and mandatory product certification stipulated by the State and shall be valid if it is subject to the surveillance audit and passed the audit.

To verify that this certificate is current please refer to:

- 1, Scan QR code on certificate
- 2, NSY Website: <http://www.nsyglobal.com>
- 3, CNCA Website: <http://www.cnca.gov.cn>

This is to certify that

**Wuxi Guo Sheng Bio-Engineering Co., Ltd.**

Uniform social credit code: 913202000502141380

**Registered address:** No.35 Huitai Road, Liangxi District, Wuxi, Jiangsu, China

**Business address:** No.35 Huitai Road, Liangxi District, Wuxi, Jiangsu, China

Medical devices Quality management system as per

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

for the following scope

Production and Distribution of PCR Tubes, PCR Plates, Elisa Plates, Petri Dishes, Pipette Tips, Deep-well Plates, Storage Tubes, Reacting tubes, and reacting Cups for In Vitro Diagnostic Use

Certificate No.: 38524MDQ0099R0M

Original Issued Date: 2024-02-29

Certificate Renewal Date:

Issued Date: 2024-02-29

Expiry Date: 2027-02-28



ISO 13485



Signature

**NSY Certification (Shanghai) Co., Ltd.**

Address: Room 1002-1003, No. 211 Jin'gang Road, Zhongxin Media Building, FTA Shanghai, Shanghai City, P.R. China

Tel: 021-50562313; E-mail: [info@nsyglobal.com](mailto:info@nsyglobal.com)