

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832699**

Certificate Holder:

NEST[®]

Wuxi NEST Biotechnology Co., Ltd.

Unified Social Credit Code: 91320213685882797G

Registration Address: No. 530, Xida Road, Meicun Industry Zone,
Xinwu District, Wuxi, 214112 Jiangsu, P. R. China

Operation Address: same as above

Scope:

Design and Development, Manufacture and Sales of Disposable
Medical Laboratory Consumables (Plastic Test Tubes, Petri
Dishes, etc.)

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2024-10-23 until 2027-10-22.

It remains valid subject to satisfactory surveillance audits.

First certification 2018

This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>



2024-09-30

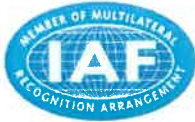

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room 1203,
12F, Building 4, No.15, Ronghua South Road, Beijing Economic-Technological
Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot Free
Trade Zone), 100176, P. R. China

www.tuv.com



 **TÜVRheinland[®]**
Precisely Right.




DAkkS
 Deutsche
 Akkreditierungsstelle
 D-ZM-11321-01-00



Product Service

Certificate

No. Q5 109429 0002 Rev. 01

Holder of Certificate: **WUXI NEST BIOTECHNOLOGY CO., LTD**
 NO.530 Xida Road
 Meicun Industrial Park
 Xinwu District
 214112 Wuxi, Jiangsu
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

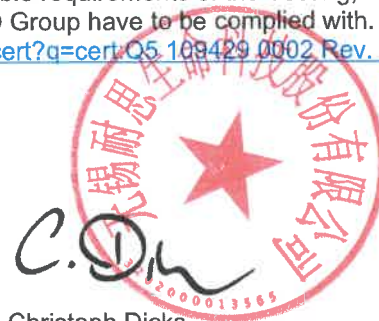


Scope of Certificate: **Design, Development, Production and Distribution of Disposable Medical Laboratory Consumables, Disposable Intranasal Atomization Devices, Specimen Collection Swabs, Pen Injectors, Disposable Pen Injector Assembly**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5.109429.0002.Rev.01

Report No.: SH25172402
Valid from: 2026-01-19
Valid until: 2028-03-20

Date, 2026-01-19



Christoph Dicks
 Head of Certification/Notified Body



Product Service

Certificate

No. Q5 109429 0002 Rev. 01

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies): **WUXI NEST BIOTECHNOLOGY CO., LTD**
NO.530 Xida Road, Meicun Industrial Park, Xinwu District, 214112
Wuxi, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Design, Development, Production and Distribution of Disposable Medical Laboratory Consumables, Disposable Intranasal Atomization Devices, Specimen Collection Swabs, Pen Injectors, Disposable Pen Injector Assembly

WUXI NEST BIOTECHNOLOGY CO., LTD
NO.105 Qunxing Road, Xinwu District, 214112 Wuxi, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Production of Disposable Medical Laboratory Consumables, Pen Injectors, Disposable Pen Injector Assembly





Product Service

Certificate

No. Q8 089489 0003 Rev. 04

Holder of Certificate: **Wuxi Futeng Irradiation Technology co., LTD**
No.530, Xida Road, Meicun
Xinwu District
214112 Wuxi, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): **Wuxi Futeng Irradiation Technology co., LTD**
No.530, Xida Road, Meicun, Xinwu District, 214112 Wuxi,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

See scope of certificate

Certification Mark:

Scope of Certificate: **The provision of RHODOTRON EB Irradiation Sterilization Services for Medical Devices**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q8 089489 0003 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q8_089489_0003_Rev.04)

Report No.: SH2393501

Valid from: 2024-01-05
Valid until: 2027-01-04

Date, 2023-12-21



Christoph Dicks
Head of Certification/Notified Body



OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEM CERTIFICATE

This is to Certify that the OCCUPATIONAL HEALTH & SAFETY MANAGEMENT SYSTEM of

Wuxi NEST Biotechnology Co., Ltd.

Registered Address: No.530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi, Jiangsu, China

Audit Address: No.530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi, Jiangsu, China

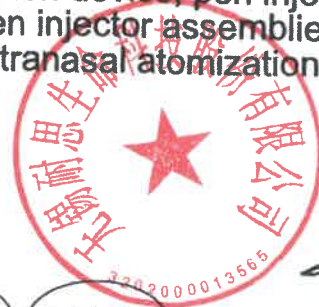
has been assessed by NOA Certification and found to comply with

GB/T 45001-2020 idt ISO45001:2018

for the scope of

Design, production, and sales of laboratory plastic consumables, medical devices (disposable intranasal atomization device, pen injector), and pharma packaging materials (COP bottles, pen injector assemblies, COP prefilled syringe assemblies, and prefilled intranasal atomization assemblies)

Certificate Number: NOA2408127
Unified Social Credit Code: 91320213685882797G
Initial Certification Date: 19 Aug. 2024



Surveillance Audit Pass Label:

Surveillance 1
Audit Pass Label

Surveillance 2
Audit Pass Label

Surveillance 3
Audit Pass Label

Certification Manager



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C051-M



Please scan the QR code above by WeChat to check certificate validity.

Certificate Issue Date: 19 Aug. 2024

Certificate Expiry Date: 18 Aug. 2027

This certificate is issued by NOA Testing & Certification Group Ltd. The certificate holder shall perform the supervision and audit in accordance with the certification and accreditation rules and the certification contract, and affix a surveillance audit pass label to maintain the validity of certificate. To verify the validity of certificate, please visit our website (www.noagroup.com) or scan the QR code above by WeChat, or visit the CNCA website (www.cnca.gov.cn).

NOA Testing & Certification Group Ltd.

Add. : 2F, Building 5, No.169, Lianchuan Road, Minhang District, Shanghai, China Email: info@noagroup.com

NOA

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE

This is to Certify that the ENVIRONMENTAL MANAGEMENT SYSTEM of

Wuxi NEST Biotechnology Co., Ltd.

Registered Address: No.530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi,
Jiangsu, China

Audit Address: No.530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi,
Jiangsu, China

has been assessed by NOA Certification and found to comply with

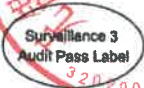
GB/T 24001-2016 idt ISO14001:2015

for the scope of

Design, production, and sales of laboratory plastic consumables, medical devices (disposable intranasal atomization device, pen injector), and pharma packaging materials (COP bottles, pen injector assemblies, COP prefilled syringe assemblies, and prefilled intranasal atomization assemblies)

Certificate Number: NOA2408126
Unified Social Credit Code: 91320213685882797G
Initial Certification Date: 19 Aug. 2024

Surveillance Audit Pass Label:



Certification Manager



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C051-M



Please scan the QR code above by WeChat to check certificate validity.

Certificate Issue Date: 19 Aug. 2024

Certificate Expiry Date: 18 Aug. 2027

This certificate is issued by NOA Testing & Certification Group Ltd. The certificate holder shall perform the supervision and audit in accordance with the certification and accreditation rules and the certification contract, and affix a surveillance audit pass label to maintain the validity of certificate. To verify the validity of certificate, please visit our website (www.noagroup.com) or scan the QR code above by WeChat, or visit the CNCA website (www.cnca.gov.cn).

NOA Testing & Certification Group Ltd.

Add. : 2F, Building 5, No.169, Lianchuan Road, Minhang District, Shanghai, China Email: info@noagroup.com



Fiscal Year 2024 FDA REGISTRATION INFORMATION

To whom it may concern,

Establishment: WUXI NEST BIOTECHNOLOGY CO., LTD

Registered Address: No.530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi,
Jiangsu, 214112, CHINA

Registration Number: 3009302820

Owner/Operator Number: 10070331

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, and the U.S. Agent information is:

U.S. Agent for FDA: SPICA MEDTECH CORP

Communications: 1020 LINCOLN ST Denver, CO, 80203, United States
Phone: 720 6176666 Ext ,Email: spica_us@yahoo.com

Establishments that are involved in the production and distribution of medical devices intended for commercial distribution in the United States (U.S.), including those that are imported for export only, are required to register annually with the FDA under section 510(g) of the Federal Food, Drug, and Cosmetic Act; And annual registration for each fiscal year is required for all establishments. Annual registration shall take place during the period beginning on October 1 and ending on December 31 of each fiscal year.

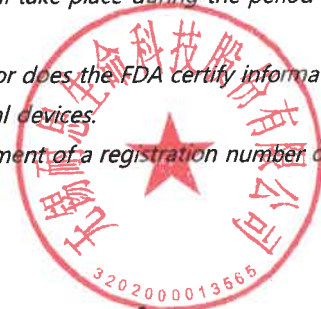
The FDA does not issue registration certificates to medical device facilities nor does the FDA certify information for facilities that have registered their establishments and listed their medical devices.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products."



For and on behalf of
SPICA MEDTECH CORP

Authorized Signature(s)



Certificate of Registration

Certificate number

192322.241127

File number

A29180

Initial issue date

2024-11-27

Cycle start date

2024-11-27

Effective date

2024-11-27

Expiry date

2027-11-26

**WUXI NEST BIOTECHNOLOGY CO.,LTD**No.530, Xida Road, Meicun Industrial Park
Xinwu District, Wuxi 214112 CHINA

Facility ID: F007679

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016**EN ISO 13485:2016/A11:2021**

Design, Development, Production and Distribution of Pen Injector, Disposable Pen Injector Assembly for Further Manufacturing of Drug-Delivery Products.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

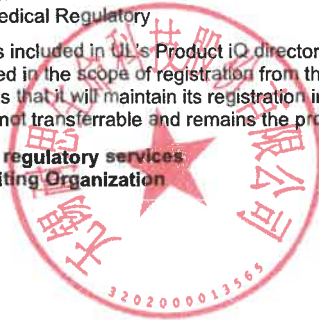
Paul Daysh

Operations manager – Medical Regulatory

Check certificate status: [here](#)

This quality system registration is included in UL's Product IQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



GREENHOUSE GAS VERIFICATION OPINION

Certificate number: 117-ICAS-THC202507158

This verification opinions are in response to:

Verified party: Wuxi NEST Biotechnology Co., Ltd.

Address: No. 530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi City, Jiangsu

Shanghai Ingeer Certification Assessment Co., Ltd. issues this third-party verification opinions in accordance with ISO14064-1:2018, ISO14064-3:2019:

- The GHG emissions of Wuxi NEST Biotechnology Co., Ltd. were 6949.49 tons CO₂ Equivalent and the GHG removal was 6949.79 tons CO₂ Equivalent for the reporting period from 1 January 2024 to 31 December 2024.
- The verification confirms that no material deviations are found in the emissions of Wuxi NEST Biotechnology Co., Ltd. and that the data and information on greenhouse gases of the verified party are fairly presented.
- The assurance level for this verification is a reasonable assurance level
- The detailed results of the verification are as follows:

Greenhouse Gas Emission Categories	Verification data (t CO ₂ e)
Direct GHG Emissions and Removals	187.46
Indirect GHG Emissions from Imported energy	6589.86
Indirect GHG Emissions from Transportation	172.47
Indirect GHG Emissions from Products Used by Organization	/
Indirect GHG Emissions Associated with the Use of Products from the Organization	/
Indirect GHG Emissions from Other Sources.	/
Total GHG Emissions	6949.79

- The GHG statement for verification is the responsibility of the verified party.

Date of certificate issue: 9 July, 2025

Certificate Issuer:

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



The ownership of the certificate belongs to Shanghai Ingeer Certification Assessment Co.,Ltd. The information & validation of this certificate can be checked on ICAS website, or by calling ICAS's clients services dept.

第二类医疗器械经营备案凭证

备案编号： 苏锡药监械经营备20230249号

企业名称	无锡耐思生命科技股份有限公司
统一社会信用代码	91320213685882797G
法定代表人	杨卫东
企业负责人	杨卫东
住 所	无锡市新吴区梅村工业园锡达路530号
经营方式	批发
经营场所	无锡市新吴区梅村工业园锡达路530号
库房地址	无锡市新吴区梅村工业园锡达路530号3层301室
经营范围	2002版批发：6816，6803，6823，6815，6808； 2017版批发：01，02，03，06，14；

备案部门（公章）：

备案日期： 2023年05月17日





医疗器械生产许可证

许可证编号：苏药监械生产许20190045号

统一社会信用代码：91320213685882797G

企业名称：无锡耐思生命科技股份有限公司

法定代表人：杨卫东

住所：无锡市新吴区梅村工业园锡达路530号

企业负责人：杨卫东

生产地址：江苏省无锡市新吴区梅村工业园锡达路530号

生产范围：II类:08-05呼吸、麻醉、急救设备辅助装置，14-01注射、穿刺器械，22-11采样设备和器具

许可期限：自 2024 年 04 月 02 日

发证部门：江苏省药品监督管理局

至 2029 年 04 月 01 日

发证日期：2024 年 04 月 11 日



编号 320200666202402060002

统一社会信用代码

91320213685882797G (1/1)

营业执照

(副本)



扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名称 无锡耐思生命科技股份有限公司

类型 股份有限公司(非上市)

法定代表人 杨卫东

经营范围 医疗器械的研发、生产、销售；生物工程技术开发、咨询、交流、转让、推广服务；实验分析仪器的研发、生产、销售；化学试剂（不含危险化学品）的销售；道路普通货物运输；自营和代理各类商品及技术的进出口（国家限定公司经营或禁止进出口的商品及技术除外）。（依法须经批准的项目，经相关部门批准后方可开展经营活动）
一般项目：模具制造；模具销售；塑料制品制造；塑料制品销售；医用包装材料制造；包装材料及制品销售（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）

注册资本 36000万元整

成立日期 2009年03月06日

住所 无锡市新吴区梅村工业园锡达路530号



登记机关



2024年02月06日