Table of contents

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Scope and Disclaimer

Dear customer, thank you for choosing NEST products. The information provided in this document is intended to assist you in applying NEST products to your production, processes, or systems.

Please note that, unless otherwise stated, NEST is only responsible for the authenticity of the NEST issued test or validation reports in this document. Additionally, NEST guarantees the authenticity of the statements made by NEST in this document. NEST also relies on test reports, documents, and other information provided by raw material suppliers and direct component suppliers to provide you with validation results. Documents from supplier sources may be requested to be provided by NEST or directly obtained from the supplier.

NEST has also commissioned third parties to conduct some tests or validations, and the authenticity of the results is guaranteed by the commissioned third parties. As of the revision date of this version, NEST believes that all the information contained in this document is accurate and reflects our knowledge truthfully. Key information of the product, such as raw materials and processing technology, will not be changed until NEST completes the full validation. If you find any discrepancies between the key information in the more recent document issued by NEST and the content of this validation report, it means that the relevant content of this validation report has expired. Please contact us to obtain an updated validation report. We will regularly review and update this document to ensure that you receive the most accurate information possible.

The tests and reports provided in this document apply to NEST products listed in the "Product List" and the scope of validation is limited to the recommended performance and application conditions of NEST products. Extra validation is required for the use beyond the performance and application scope stated by NEST, or contact us for additional testing.

Finally, if you have any feedback on the content of this document or have more detailed requirements for the information in this document, please feel free to contact NEST via the phone or email provided below. We are happy to have our products undergo more testing and challenges, and further improve our products and services.

Below are our contact details:
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Chapter 1 Introduction and Overview

1-1 Company Profile

Leading comprehensive service provider in the field of life sciences in China

Wuxi NEST Biotechnology Co., Ltd. (hereinafter referred to as "NEST") was established in 2009 and created the NEST® brand. With the belief of "producing high-end consumables and creating internationally renowned brands," NEST focuses on the research and development and manufacturing of products in the field of life sciences. NEST has 6,800m^2 of Class 100,000 clean-rooms, 2,700m^2 of Class 10,000 clean-rooms, mature production processes, advanced machinery and equipment, a professional research and development center, and a senior management team. It is a leading comprehensive service provider for the multi-field development in the life sciences industry in China.

In 2020, the company officially changed its name to Wuxi NEST Biotechnology Co., Ltd.

Establishment of overseas subsidiaries

The NEST brand continues to explore overseas markets. In 2013, the US subsidiary was officially established. In 2022, subsidiaries in Rotterdam, the Netherlands, Sharjah, United Arab Emirates, and Tokyo, Japan were established. The new warehouse in the western United States has been completed, providing integrated storage, transportation, and sales services, guaranteeing the supply of NEST products in overseas markets. With the continuous increase in overseas business volume, NEST's footprint has spread all over the world and is exported to many countries and regions including North America, Europe, Southeast Asia, the Middle East, Japan, South Korea, and India.

Introduction of advanced equipment to ensure quality stability

To ensure stable quality and achieve seamless integration of "raw material procurement - production - packaging - sterilization - delivery," NEST invested 150 million in 2012 to build a 27,000m^2 plant with dust-free clean-rooms and introduced the international advanced electron irradiation equipment Rhodotron-TT200 (irradiation sterilization process certified by ISO13485 and ISO11137 quality systems). NEST also imports medical-grade raw materials that meet USP Class VI standards and standardized production in accordance with GMP quality management specifications. It has obtained ISO 9001, ISO 13485, ISO 11137, FDA, CE certification, and medical device production licenses. In 2021, NEST added 4,500m^2 of Class 100,000 clean-rooms

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and 1,500m^2 of Class 10,000 clean-rooms for the production of medical devices and pharmaceutical packaging consumables.

NEST product line - laboratory consumables, medical devices, pharmaceutical packaging consumables, laboratory instruments, biological reagents

NEST products mainly include disposable consumables (cell biology, bioprocessing, liquid handling, general testing, molecular biology consumables), medical devices, innovative pharmaceutical packaging consumables, laboratory instruments, and biological reagents (cell culture reagents, testing reagents, etc.). They are widely used in new drug development, vaccine research and production, cell therapy, medical aesthetics, biomedical research, *in vitro* diagnostics, and other fields. NEST products have wide coverage, comprehensive specifications, and complete qualifications to meet different customer needs.

Customization services

Wuxi NEST Biotechnology Co., Ltd. has strong capabilities in mold design, precision machining of machine tools, and plastic molding. In addition to selling standard products, we also provide various customized services to the industry.

1-1-1 Production Base and Warehouses

NEST Headquarter

Departments and Functions: Research, Production, Marketing, Sales, Warehousing.

Location: Wuxi, Jiangsu, China

US Branch

Departments and Functions: Marketing, Sales, Warehousing.

Mainly serving countries and regions: North America, South America

Research and Warehousing Base in Woodbridge, New Jersey, USA

Warehousing area: 3300m^2

Location: Woodbridge, New Jersey, USA

Warehouse in Phoenix, Arizona, USA

Warehousing area: 4500m^2

Location: Phoenix, Arizona, USA

Netherlands Subsidiary

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Departments and Functions: Sales, Warehousing

Location: Rotterdam, Netherlands

Mainly serving European regions

United Arab Emirates Subsidiary

Departments and Functions: Sales, Warehousing

Location: Sharjah, United Arab Emirates

Mainly serving the Middle East and North Africa regions

Japan Subsidiary

Departments and Functions: Sales

Location: Tokyo, Japan

Mainly serving East Asia regions

We are also actively expanding our warehouse network and business scope to better serve our customers. We believe that NEST's global vision and warehouse layout will bring more value and advantages to our customers.

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1-2 Quality Compliance, Registration and Certification

NEST evaluates, controls and manages the quality of its products according to relevant national or international standards. NEST also ensures quality compliance and registration certification to ensure the safety, reliability, and effectiveness of its products, as well as to meet national and international legal requirements. These measures aim to reduce product quality issues and risks and improve production efficiency and management level. If you need to obtain NEST's quality compliance and registration certificates, please refer to the appendix or download them from the official website www.cell-NEST.com.

1-2-1 ISO9001, ISO 13485

ISO9001 is a certification for quality management systems applicable to organizations of various types and sizes. Its purpose is to help organizations achieve customer satisfaction and continuously improve their business processes. ISO13485 is a certification for medical device quality management systems, applicable to manufacturers, suppliers, and distributors, ensuring that their products comply with relevant regulations and legal requirements for medical devices.

NEST's ISO9001 and ISO13485 certifications are authorized by TÜV Rheinland, an authoritative EU notified body. TÜV Rheinland Group is authorized to conduct assessments for industrial and consumer products to ensure that NEST's products comply with most EU directives and regulations.

1-2-2 CE Certification: EU MDR

CE MDR is the latest European Union regulation for medical devices. Its implementation strengthens the regulation of the safety and effectiveness of medical devices, standardizes the medical device market, and ensures public drug safety and health. NEST's relevant products comply with the regulations of CE MDR, ensuring that the production of medical devices meets the relevant EU laws, regulations, and technical standards, and possesses safety and effectiveness. NEST obtained the CE certificate authorized by TÜV SÜD, an authoritative institution accredited by the European Union, in 2020.

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1-2-3 FDA Registration

Since 2011, NEST has registered and sold its products with the US FDA. Our products comply with relevant US laws, regulations, and technical standards, and possess safety and effectiveness.

1-2-4 Medical Device Production License

NEST obtained a medical device production license in 2021. We have various medical device products, including reusable pen injectors and disposable nasal drug delivery atomization devices. High-precision pen injectors are challenging medical devices that require high-precision processing equipment and technology, as well as strict quality control. Therefore, for companies to obtain a production license for high-precision pen injectors, they need to have high technical capabilities and quality assurance. We apply the same technical capabilities and quality control requirements to our laboratory consumables.

1-3 Quality Management System

NEST quality management system is implemented in accordance with the requirements of ISO9001, ISO13485, and relevant national and international regulations, and has obtained relevant certifications. NEST takes various measures such as employee management and training, equipment validation, supply chain management, and production environment control to ensure the stability and reliability of product quality. If you need to review related system documents, records, etc., please contact us for on-site factory inspection, and we will provide corresponding information.

1-3-1 Personnel

NEST emphasizes the management and training of employees, ensuring that all employees strictly adhere to the requirements of the operating instructions through on-boarding training, job training, regular rotation training, and job rotation training, to ensure that the entire product production process complies with the validated process requirements.

1-3-2 Production and Testing Equipment Validation

NEST releases all machinery and equipment (including production equipment and testing

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equipment) for the production process through three stages: installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ), to ensure that the equipment parameters meet the design requirements and can guarantee stable and reliable product performance. Testing equipment is also regularly tested and calibrated. These equipment include but are not limited to:

Production equipment:

- Injection molding machine and corresponding molds
- Automatic assembly equipment, welding equipment, surface treatment equipment, automatic packaging equipment, etc.

Testing equipment:

- Leak testers, flatness gauges, insoluble particle detectors, angle measurement devices, etc.

1-3-3 Incoming Material Control

NEST also implements strict control over supplier admission and approval of raw materials/packaging materials. The company ensures that all raw materials/packaging materials meet product technical requirements through layered control in the following steps:

- Supplier questionnaires
- Supplier on-site audits
- Raw material/packaging material report review
- Raw material/packaging material performance validation
- Raw material/packaging material batch inspection

The implementation of these measures ensures the stability of the supply chain and the quality of the products. This section will also include NEST's relevant statements regarding the control of raw materials and packaging materials.

1-3-3-1 Raw Material Compliance Statement (USP Class VI)

The raw material particles or finished products used in NEST products are provided by manufacturers that meet relevant tests for USP Class VI, ISO 10993, or GB/T 16886, including but not limited to PS, PC, PET, PETG, PP, and others. At the same time, NEST products are rigorously tested by third-party laboratories (with CNAS or CMA qualifications) according to the following standards to ensure compliance with the relevant requirements.

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Test Item	Test Standard
In vitro cytotoxicity test	GB/T 16886.5-2017 (corresponding to ISO 10993-5:2009, USP<87>)
Skin sensitization test	GB/T 16886.10-2017 (corresponding to ISO 10993-10:2010, USP<88>)
Acute systemic toxicity test	GB/T 16886.11-2011 (corresponding to ISO 10993-11:2017, USP<88>)
In vitro hemolysis test	GB/T 16886.4-2003 (corresponding to ISO 10993-4:2002)
Skin irritation test	GB/T 16886.10-2017 (corresponding to ISO 10993-10:2010, USP<88>)

1-3-3-2 TSE/BSE/GMO Statement

All products in this binder produced by NEST do not use any animal-derived or genetically modified ingredients or tissues throughout the entire production process, and have no TSE/BSE/GMO risks.

1-3-3-3 REACH

NEST strictly complies with the EU regulation "Registration, Evaluation, Authorization and Restriction of Chemicals" (2006/1907) (REACH) and controls the highly concerned substances (SVHC) in the raw materials.

1-3-4 Production Environment Control

1-3-4-1 Qualification of 100,000 and 10,000 Level Clean-Rooms

NEST has multiple clean-rooms that meet ISO14644 Class 7/8 standards. They undergo periodic monitoring by third parties to ensure compliance with product manufacturing and packaging requirements. Please contact us through our official website or email to obtain the clean-room qualification testing report.

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1-3-4-2 Methods for Clean-Room Environmental Control

NEST conducts periodic monitoring of dust particles, airborne bacteria, settle plate counts, air exchange rates, temperature, humidity, pressure differentials, and compressed air in clean-rooms, in accordance with ISO14644 requirements and company procedures, to ensure compliance with regulatory requirements for clean-room environments.

1-3-4-3 Qualification of Sterility Testing Laboratory

NEST has a Biosafety Level 2 (BSL-2) sterility testing laboratory. It conducts testing of the production environment according to clean-room environmental testing procedures to ensure the safety and reliability of the production environment, and that the final products meet customer requirements.

1-3-4-4 Purified Water System Validation

NEST has multiple purified water systems used for cleaning clean-rooms, clean-room garments, and tools, ensuring the quality of water used in clean-rooms. The company conducts periodic water point testing to test the properties, acidity/alkalinity, ammonia, conductivity, nitrates, nitrites, oxidizable substances, non-volatile matter, heavy metals, and microbiological limits of purified water, to ensure compliance with the requirements of the Chinese Pharmacopoeia (2020 edition) and European Pharmacopoeia(2020) <Purified Water> section.

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1-4 Product Verification and Quality Control

During the product validation process, NEST will test all performance items of the product according to internal product technical requirements to ensure that the product meets the design requirements. NEST products go through product design validation, process window validation, performance validation, small-batch trial production, and three-batch production tracking during the development stage to ensure that the products are produced stably and reliably, meeting the product design requirements.

After the product validation is completed and mass production is achieved, some of the early-stage validated product performance test items will be transformed into periodic monitoring and batch testing items to control the consistency of product quality. Periodic monitoring is conducted regularly based on different products and test items, while batch testing is conducted before each batch of product processing and release to ensure that any product quality issues are promptly identified, intercepted, and corrected during the production process.

1-4-1 Product Performance Validation

Product performance validation refers to a series of tests and validations to check whether the product meets the predetermined performance parameter requirements and user usage needs. The results of the validation can be used to determine whether the product can enter the next stage of development or production. These validations include, but are not limited to:

- Application performance validation of finished products
- Biocompatibility testing of finished products
- Extractable and leachable substance testing of finished products
- Shelf life validation of finished products
- Transportation validation of finished products

1-4-2 Periodic Monitoring

Periodic monitoring of products refers to regular testing and evaluation of finished products to ensure that they continue to meet quality and performance requirements during use. This type of monitoring helps identify problems with the production process or quality testing process that have a moderate level of risk and take necessary measures for repair or replacement in a timely manner. Periodic monitoring varies depending on the product type and purpose, including, but not

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limited to:

- Sterility testing
- Nuclease testing
- Endotoxin testing
- Insoluble particle testing

1-4-3 Batch Testing

Process inspection and batch release testing are important methods for product quality management, which can control the quality of semi-finished products and pre-released finished products, ensuring stability and consistency of product quality. The advantage of batch testing is the ability to detect problems as soon as possible throughout the entire process, thereby reducing production costs and improving product quality. These testing items include, but are not limited to, the following for semi-finished and finished products:

- Dimensional inspection
- Appearance inspection
- Semi-finished product application performance testing
- Component compatibility testing
- Random sampling of finished product application performance
- Packaging and boxing inspection

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1-5 Electron Beam Sterilization and Sterility Assurance

Electron beam sterilization is an efficient sterilization method that has been widely used in industries such as medical devices, pharmaceuticals, and food. It has many advantages compared to gamma radiation sterilization, including lower maintenance costs, faster processing time, higher processing capacity, and no generation of radioactive waste or hazardous substances. The use of electron beam sterilization is a trend driven by policies and environmental requirements.

1-5-1 ISO 11137

NEST's electron beam sterilization process complies with the ISO11137 quality system, which adds a certification system for product sterilization on the basis of ISO13485. NEST's subsidiary, Futen, obtained the ISO certification authorized by TÜV SÜD, an authoritative institution accredited by the European Union, in 2020. The electron beam sterilization process of NEST products is validated and carried out by Futen, including the validation process of bioburden assessment, sterilization dose setting and loading method validation, sterile packaging validation, and sterility inspection.

After electron beam sterilization, NEST products can achieve a sterility assurance level (SAL) of 10^{-6}, ensuring the sterility of the parts in contact with liquids. The basis for electron beam sterilization includes the sterilization label on the product outer packaging, COA, COC, and irradiation process validation report. If you need to obtain the relevant test reports, please contact us.

1-5-2 Bioburden Assessment

Bioburden refers to the number and types of microorganisms present on the surface or object before sterilization. Its assessment is carried out to ensure an appropriate sterilization dose is applied to all microorganisms present on the product, effectively killing them. NEST's bioburden assessment method for products involves initial microbial contamination testing according to the relevant standard ISO 11737-1 and GB/T 19973.1-2015. In addition, NEST also controls the level of initial contaminants by periodically monitoring the cleanliness of the clean-rooms.

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1-5-3 Sterilization Dose Setting and Loading Method Validation

After setting the minimum sterilization dose based on the initial contamination level, irradiation is performed during the actual production of the product according to the recommended optimal dose of ±10% as per ISO11137-2, and GB/T 19973.1-2015. The loading method for NEST products during sterilization is based on the characteristics of the internal structure of the product. Through operational qualification (OQ) testing, an optimized distribution of sterilization dose is achieved, ensuring a sterility assurance level (SAL) of 10^{-6} for NEST products.

1-5-4 Sterile Packaging Validation and Sterility Inspection

NEST performs sterile packaging validation on products that have undergone accelerated aging according to ASTM's packaging leakage standard test methods. Regular sterility inspections are conducted to provide additional validation of the electron beam sterilization process.

NEST's Biosafety Level 2 (BSL-2) sterility testing laboratory conducts sterility inspections of products according to the product testing specifications to ensure the safety and reliability of the production environment, as well as the effectiveness and reliability of the electron beam sterilization process, in order to produce final products that meet customer requirements.

1-6 Supply Chain Stability and Lead Time

To ensure the stability of the supply and timely delivery, NEST employs the following measures to manage the supply chain and lead time:

- Long-term supply contracts: NEST signs long-term supply contracts with customers to ensure stable supply over a certain period of time.
- Safety stock: To address unforeseen circumstances during production, the company maintains a certain quantity of safety stock.
- Timely scheduling: Based on customer orders and inventory status, NEST adjusts production plans promptly to ensure timely delivery.

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1-7 Traceability

NEST maintains the following methods to trace the production and transportation processes of its products:

- Batch information: Information about each product batch is recorded through batch coding, which enables traceability of key process inspection data and test results. Customers can use this information to trace the production of the product.
- Production records: In NEST's production process, process inspection data is retained at each process step, including raw materials, injection molding, and other product processing techniques. This data can be used to trace the production of the product.
- Sample retention: Samples are retained for each batch of products, allowing customers to trace the production of the product.
- Transportation process inspection: In addition to the production process, NEST also conducts inspections of the transportation process to ensure that the products are not damaged or compromised in quality during transportation.

1-8 Shelf Life

NEST determines the shelf life of products by conducting accelerated aging tests in accordance with YY/T 0681.1-2018 or ASTM F1980. The start time for calculating the shelf life is the production period of the product, as indicated by the batch-numbered accompanying COA/COC of NEST products. The duration of the shelf life for general products can be found in the COA/COC and the official product technical documents on the website.

Unless otherwise specified, the general storage conditions for NEST consumable products include a relative humidity not exceeding 80%, an ambient temperature of 10-30℃, and a light-free environment. During transportation, precautions should be taken to prevent mechanical impact or contact with sharp objects, avoid exposure to sunlight and rain, ensure intact packaging, and prevent product contamination. Air transportation is not recommended.

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Chapter 2 NEST BioFactory

2-1 Introduction

The cultivation of mammalian adherent cells has been used in the industrial production of vaccines, monoclonal antibodies, and more. The traditional roller bottle process initially used glass material, which had a high risk of contamination and involved extensive cleaning and validation processes. As a result, disposable cell culture vessels have gradually gained favor among industrial customers. However, disposable roller bottles also have a series of issues, such as high manual workload, low productivity, poor process controllability, and difficulty in achieving uniformity between bottles.

NEST Multi-layer Cell Culture Vessels (BioFactories) are designed to replace traditional roller bottle culture techniques. The BioFactory maximizes the utilization of cultivation area in limited space, saving a significant amount of facility space and reducing production costs. It also enables automation and standardization. The design of NEST BioFactory allows for linear scalability without compromising the kinetic conditions for cell growth.

With the rapid development of biopharmaceuticals, vaccines, monoclonal antibodies, and other fields, BioFactories have been widely applied. NEST BioFactory's product quality has gained widespread recognition. The available specifications include single-layer, 2-layer, 4-layer, 5-layer, 6-layer, 10-layer, 15-layer, and 40-layer, catering to different production needs. Additionally, NEST has introduced a closed system solution for sterile liquid transfer during production.

2-2 Overview of BioFactory Product Line

The NEST BioFactory product line covered by this report includes the following different specifications:

- Number of BioFactory layers: 1 layer, 2 layers, 4 layers, 5 layers, 6 layers, 10 layers, 15 layers, and 40 layers. Suitable for different throughput.
- Opening types: 2 wide mouth, 2 narrow mouth, wide and narrow mouth. Used to match different cap types and closed system tubing types;
- BioFactory accessories (including closed systems and accessories):
  - Cap types: wide mouth plug seal cap, wide mouth vent cap, narrow mouth plug seal

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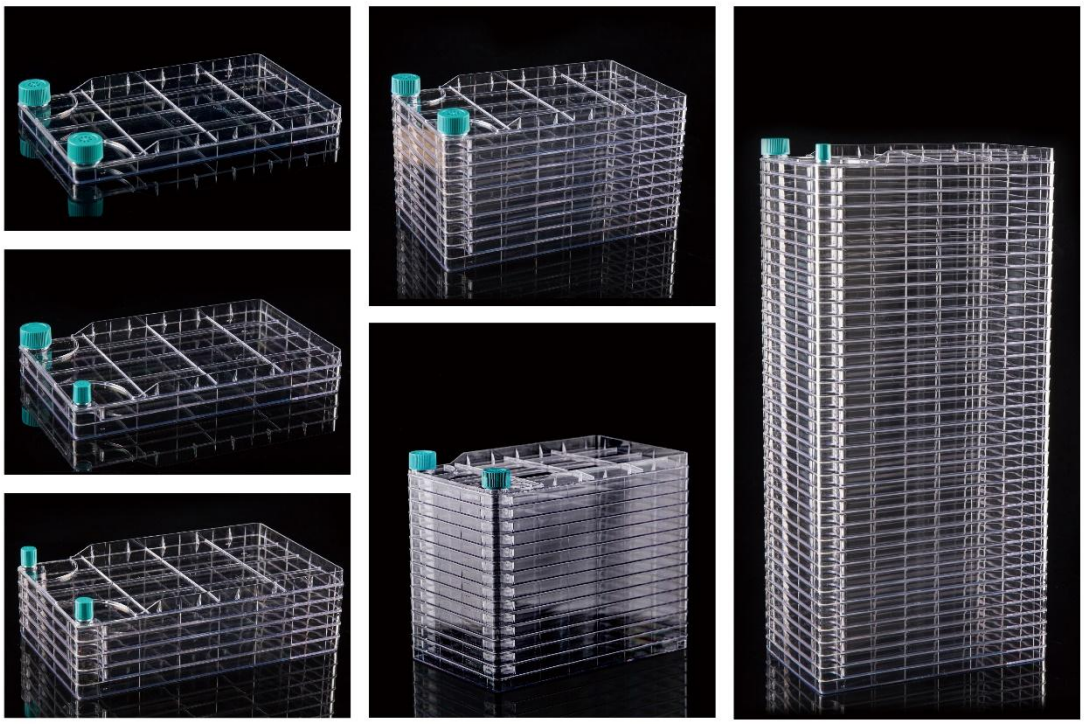
cap, narrow mouth vent cap, wide to narrow mouth adaptor cap (preinstalled with vented overcap), vented overcap, sealed overcap, adapter cap for 3/8 inch ID tube, adapter cap for 1/4 inch ID tube;

- Tubing types: platinum cured silicone tube or TPE tube, ID, OD and length customizable;
- Connector types: CPC quick connectors, heat sealed end or others;
- Adapters: Y-shaped tube connector, T-shaped tube connector, narrow-mouth adaptor connector, etc.;
- Vent air filter: filter membrane pore size 0.22 μm, membrane area 20 cm^2/13.8 cm^2;
- Others: hose clamps, holder, etc.

Please see the appendix for specific product numbers and specifications.

Product photos



1-layer, 2-layer, 5-layer, 10-layer, 15-layer, 40-layer BioFactory

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Caps

Narrow mouth vent cap 740111

Wide mouth vent cap 740011

Wide mouth plug seal cap 740001

Narrow mouth plug seal cap 740101

Vented overcap 740913

Adaptor cap preinstalled with vented overcap 740213

Sealed overcap 740901

Wide to narrow mouth adaptor cap 740201

Adapter cap for 3/8" ID tube 740302

Adapter cap for 1/4" ID tube 740402

Connectors

CPC quick connector 747001

CPC connector plug 747011

Narrow-mouth adaptor connector 741001

T-shaped connector 749001

Y-shaped connector 751001

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Tubes/Hose clamps

Platinum cured silicone tube 744001

TPE weldable tube 746001

Hose clamp 743001

Filter and assemblies

13.8 cm^2 air filter 742011

20 cm^2 air filter 742001

Filter assemblies

Inlet and outlet tubing assemblies

Accessories package 745001

BioFactory holder 751101

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2-3 Product Parameters

Product name	BioFactory
Material	Body: Polystyrene (PS), USP Class VI compliant Cap: Polypropylene (PP), USP Class VI compliant Gas-permeable membrane: Polytetrafluoroethylene (PTFE), USP Class VI compliant For detailed information, refer to the section on raw materials.
Dimensions	See appendix for details
Sterilization	Electron beam sterilization, sterility assurance level: SAL=10^{-6}. This product has been irradiated and dose released in accordance with ANSI/AAMI/ISO 11137.
Shelf life	3 years from the date of production (assuming intact packaging)
Non-pyrogenic	Reference USP<85> and "Chinese Pharmacopoeia" endotoxin test method, endotoxin level <0.05 EU/mL.
Insoluble particles	Reference USP<788> and "Chinese Pharmacopoeia", insoluble particle test method, ≤ 25 particles/mL for particles ≥10μm, ≤ 3 particles/mL for particles ≥ 25μm.
DNase/RNase-free	Reference USP<1225><1130> and "Chinese Pharmacopoeia", nucleic acid enzyme test method, tested DNase/RNase-Free.
BSE/TSE/GMO	No animal-derived or genetically modified ingredients or tissues, no TSE/BSE/GMO risks.
Cell culture performance	Logarithmic growth phase HeLa, L-929, Vero, MRC-5 cells were taken to prepare cell suspensions at suitable concentrations. The cells were inoculated and cultured in a 5% carbon dioxide incubator. After 48h or 72h, the cells were counted. The proliferation factor, cell attachment, morphology, uniform distribution, and good growth status were observed.
Production environment and raw materials	Production in a class 10,000 clean environment, raw materials comply with USP Class VI standards.
Structural design features	One-piece injection molded inlet and outlet, good sealing and firm type. Wider liquid inlet channel to prevent liquid leakage. Large opening for direct pouring of culture medium, small mouth

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	for aseptic closed system operation. The vented cap of the 0.22μm hydrophobic filter is used for contamination-free gas exchange.
Process features	Ultrasonic welding, without any foreign substances, no addition of any chemicals, eliminating the risk of unknown leachables. Excellent welding line design can avoid the generation of particles during the welding process and improve mechanical strength. Flatness and perpendicularity control to meet the conditions for uniform cell growth. Passed the sealing pressure test to prevent leakage, suitable for peristaltic pump pressurization. TC treatment, conducive to cell adhesion and growth, suitable for large-scale cultivation of adherent cells.
Packaging features	Traceable code on the packaging for product traceability. Double-layer packaging inside and outside to ensure product cleanliness and adaptability to clean environment use.

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2-4 Product Raw Materials and Packaging Information

- BioFactory body

PS - Finished product passed USP VI testing

- Main components

  Wide mouth vent cap 740011, Wide mouth plug seal cap 740001, Wide to narrow mouth adaptor cap 740201, Adapter cap for 3/8" ID tube 740302, Adapter cap for 1/4" ID tube 740402

  PP - Compliant with USP Class VI

  Narrow mouth vent cap 740111, Narrow mouth plug seal cap 740101

  HDPE - Compliant with FDA 21CFR 177.1520

  Vented overcap 740913, Sealed overcap 740901

  LDPE - Compliant with FDA 21CFR 177.1520

  Gas-permeable membranes

  PTFE - Compliant with USP Class VI

- Product inner packaging

Multi-layer composite plastic: Compliant with the standards of USP<661>, QB/T 1571-1993 and YBB00132002-2015 "General Rules for Medicinal Composite Films and Bags"

- Other parts:

  Platinum cured silicone tube 744001 : Platinum cured silicone - USP VI grade

  TPE weldable tube 746001: TPE - USP VI grade

  CPC quick connector 747001, 747011: PC - USP VI grade

  Y-shaped connector 751001, T-shaped connector 749001: PP

  Narrow-mouth adaptor connector 741001 : PTFE

  Air filter 742001, 742011: PTFE membrane, PP shell

  Hose clamp 743001: POM;

  BioFactory holder 751101: Aluminum alloy

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2-5 Validation Documents for Closed System Components

Please refer to the NEST official website for the relevant validation documents of closed system products.

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Chapter 3 Product Testing

3-1 Product Testing Summary

Product Performance Verification Tests	Periodic Monitoring Tests	Batch Release Tests
Cell Culture Testing	Cell Culture Testing	Appearance
Cell Growth Uniformity Testing	Sterility Check	Hydrophilicity Testing
Contact Angle Stability Testing	Insoluble Particle Check	Flatness, Planeness, and Perpendicularity Testing
Inter-batch Cell Growth Stability Testing	Endotoxin Check	Pressure Retention Testing
Pressure Retention Testing	Nuclease Testing	
Shelf Life Testing		
pH Stability Testing		
Temperature Distribution Testing		
Drop and Transport Testing		
Biocompatibility Testing		
Extractables Testing		
Initial Contaminants Testing (Irradiation Validation)		

In addition to the test report attached to this chapter, please contact us for the originals of other test reports.

Product Performance Verification Tests

Cell Culture Testing: Cultivation of HeLa, L-929, Vero, MRC-5 cells, etc. using 2-layer biofactories. The cells in the 2-layer cell factories exhibit normal morphology, even distribution, and good growth status. The cell proliferation rate is within the normal range.

Cell Growth Uniformity Testing: Staining the Vero cells cultured in a 10-layer BioFactory with crystal violet. The staining of crystal violet is uniform in each layer.

Contact Angle Stability Testing: A single piece of TC is naturally aged at different time intervals, with 10 test points selected for each piece. The contact angle is tested using a contact angle tester, with the contact angle ≤39°, meeting the company's standards.

Inter-batch Stability Testing: Six different batches of 2-layer cell factories are selected, with

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Vero cells cultured. The cell growth state and multiplication rate are observed. The cell morphology is normal, distributed evenly, and the growth condition is good.

Pressure Retention Testing: A 40-layer cell factory is selected and subjected to a stamping pressure. After oner repeat, the welds remain intact with no air leakage.

Shelf Life Validation: The samples undergo accelerated aging, meeting sealing and sterility requirements, confirming the product's shelf life. The results show that after aging, the product inside the packaging remains sterile, with the seal test passing, ensuring the product's shelf life is 3 years.

pH Stability Testing: Phosphate buffer solutions are added to 10-layer biofactories and placed at 37°C to observe whether the pH changes significantly. The aim of this test is to confirm that the cell factory does not contain extractables or leachables that would alter the pH of the culture medium.

Temperature Distribution Testing: The temperature variations of the 40-layer biofactory are tested and recorded during its use. This test aims to verify the uniformity of temperature changes in each layer of the culture medium.

Drop and Transport Validation: The packaged finished products undergo long-distance transportation and drop testing using actual transportation methods. Bumps, handling, and drops during transportation do not cause damage to the product or packaging.

Biocompatibility Testing: The product undergoes USP Class VI-level validation according to the relevant testing methods of GB/T 16886.

Extractables Testing: Heavy metals (lead, tin, cadmium, chromium), ignition residue, extractables (reducing substances, acidity/alkalinity, UV absorbance, appearance) are tested according to the GB/T 14233.1-2008 standard, with all values not exceeding the standard limits.

Initial Contaminants Testing: The product undergoes a biological load assessment based on GB/T 19973.1-2015 and controls the level of initial contaminants.

Periodic Monitoring Tests

Sterility Check: After sterilization treatment of the packaged products, conducting sterility testing on the samples referencing ISO11737-2:2019, Chinese Pharmacopoeia(2020) and GB/T 19973:2-2018. The test samples show no microbial growth, and the positive and negative controls show no abnormalities. Sampling is conducted proportionally.

Insoluble Particle Check: Conducting insoluble particle testing on the samples referencing USP<788> and "Insoluble Particle Inspection Method" in Chinese Pharmacopoeia(2020). Preparing the testing solution by adding water for particle inspection in proportion to the cultivation area of the samples. Each sample is tested three times. The requirements are: ≤25 particles/mL for particles ≥10μm, and ≤3 particles/mL for particles ≥25μm. Sampling is conducted

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proportionally.

Endotoxin Check: Testing the endotoxin content of the samples referencing USP<85> and relevant methods in Chinese Pharmacopoeia(2020). The endotoxin content should be ≤0.05 EU/mL. Sampling is conducted proportionally.

Nuclease Testing: Using qPCR to amplify the extract from the cell culture bottles referencing USP<1225><1130> and relevant methods in Chinese Pharmacopoeia(2020). The samples should not detect Dnase and Rnase, under the condition that the positive and negative controls show no abnormalities. Sampling is conducted proportionally.

Batch Release Tests

Appearance: According to the inspection standards of the BioFactory process, the appearance of the product is controlled using visual and caliper measurement methods.

Hydrophilicity Testing: According to the inspection standards of the BioFactory process, test the hydrophilic angle of each layer of the BioFactory surface after TC treatment.

Flatness, Planeness, and Perpendicularity Testing: According to the inspection standards of the BioFactory process, test the flatness of each layer of the BioFactory after injection molding.

Pressure Retention Testing: The BioFactory is pressurized, and if there is no air leakage, it is considered qualified. Full inspection is performed on finished products.

Attachment: BioFactory culture area and recommended working volume

BioFactory layers	Culture area (cm^2)	Medium volume (mL)	Wash Buffer volume (mL)	Digestion Buffer volume (mL)	Digestion Termination Buffer volume (mL)
1	632	150-200	30-40	20	25
2	1264	300-400	60-80	40	50
4	2528	600-800	120-160	80	100
5	3160	750-1000	150-200	100	125
6	3792	900-1200	180-240	120	150
10	6320	1500-2000	300-400	200	250
40	25280	6000-8000	1200-1600	800	1000

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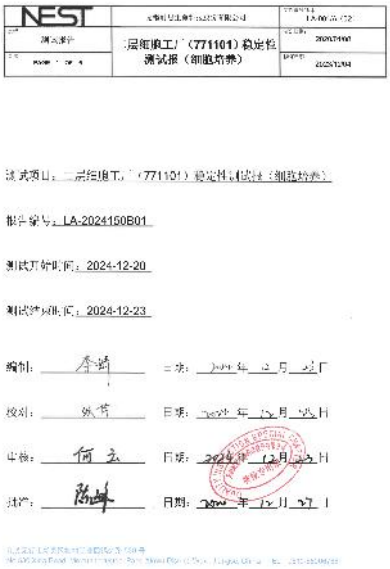
The following reports are for demonstration purposes only. If you require the original reports, please contact a NestBio sales representative.

3-2 Inter-batch Cell Growth Stability Testing



二层细胞工厂（771101）稳定性测试报（细胞培养）

报告编号：LA-2024150B01

测试开始时间：2024-12-20

测试结束时间：2024-12-23

编制：

日期：

校对：

日期：

审核：

日期：

批准：

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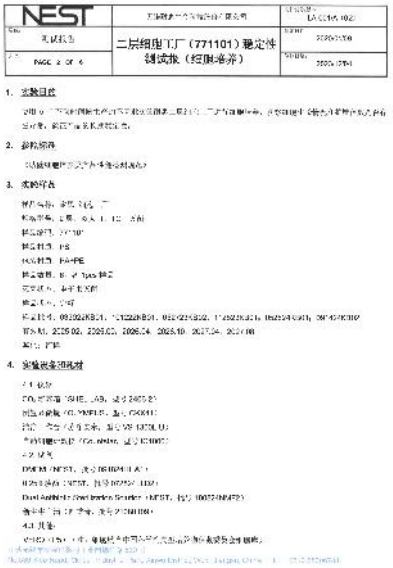


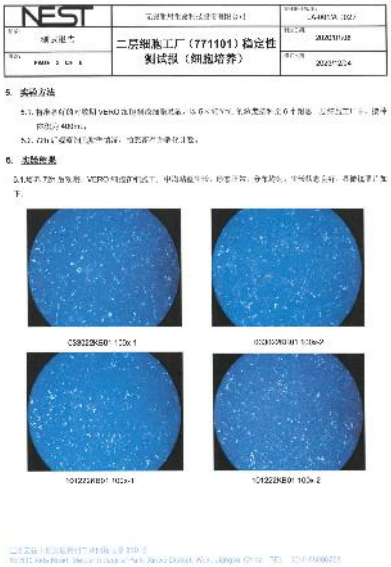
二层细胞工厂（771101）稳定性测试报（细胞培养）

1. 实验目的

2. 实验原理

3. 实验样品

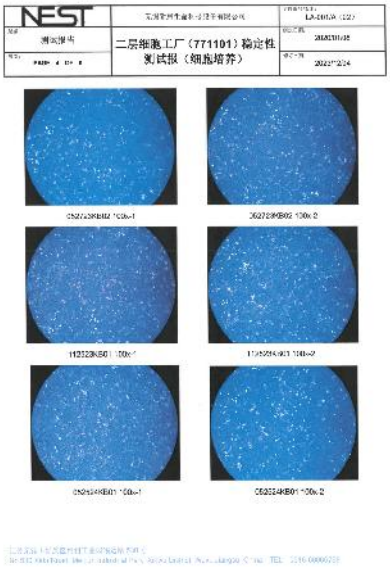
4. 实验设备和耗材



二层细胞工厂（771101）稳定性测试报（细胞培养）

5. 实验方法

6. 实验结果



二层细胞工厂（771101）稳定性测试报（细胞培养）

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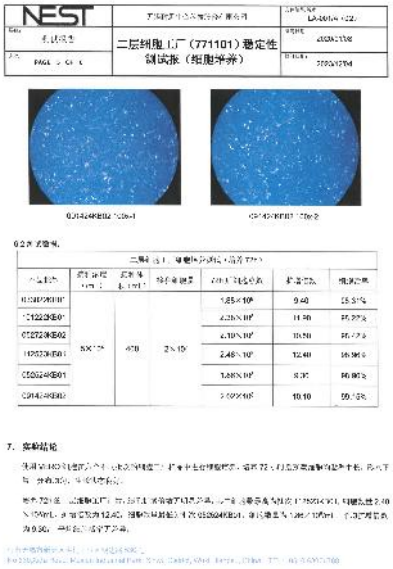
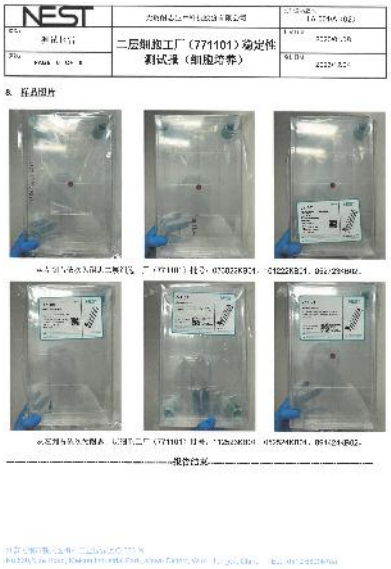


二层细胞工厂（771101）稳定性测试报（细胞培养）



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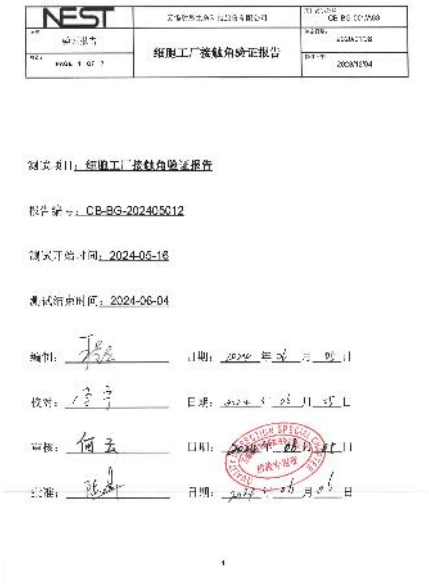
3-3 Contact Angle Stability Testing Report



细胞工厂接触角验证报告

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报告编号：CB-BG-202405012

测试开始时间：2024-06-18

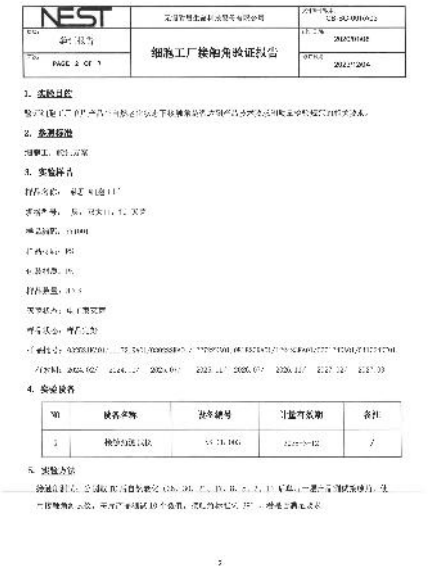
测试结束时间：2024-06-04

编制：　　日期：

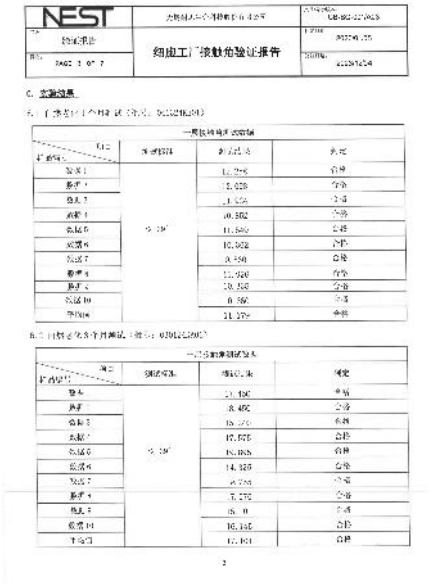
校对：　　日期：

审核：　　日期：

批准：　　日期：



细胞工厂接触角验证报告



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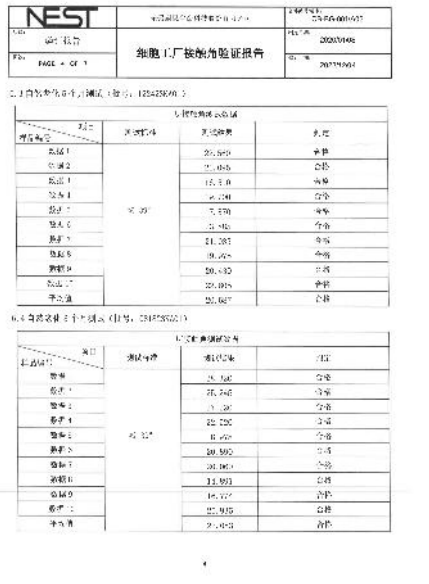

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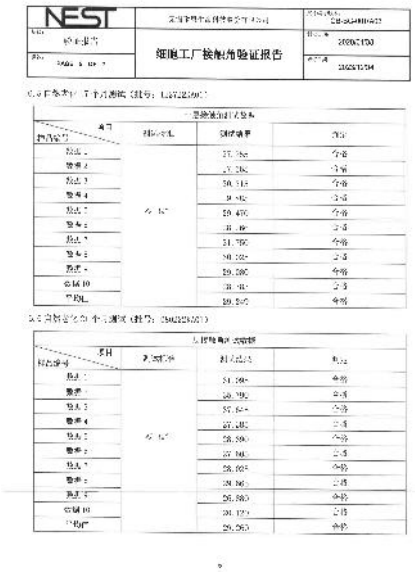

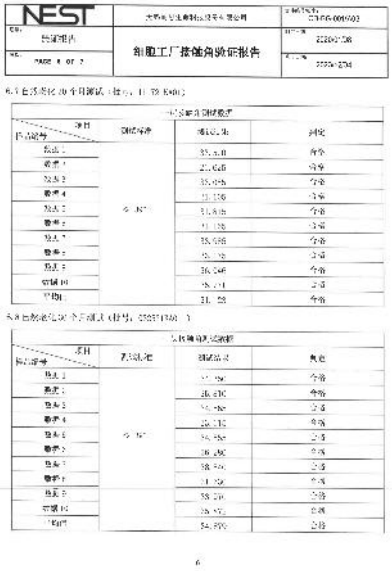

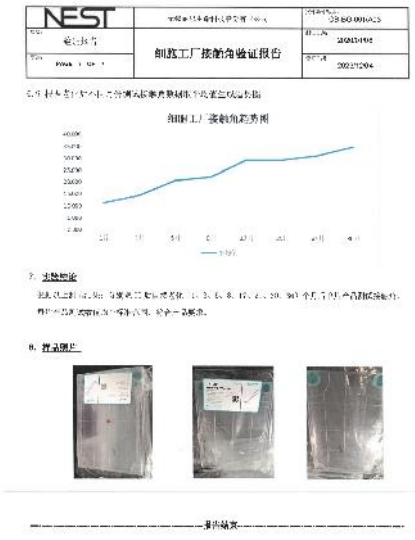

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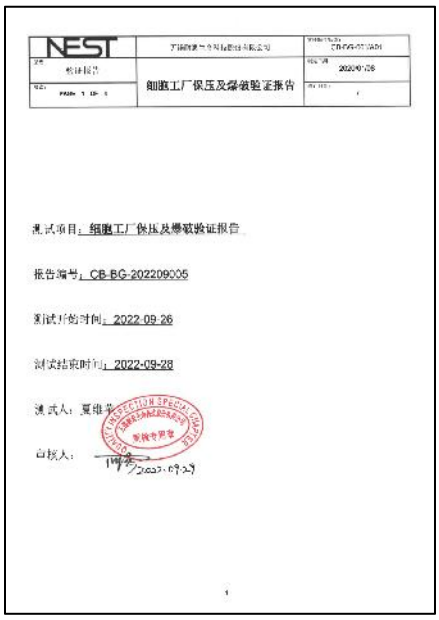
3-4 Pressure holding Report



细胞工厂保压及爆破验证报告

测试项目：细胞工厂保压及爆破验证报告

报告编号：CB-BG-202209005

测试开始时间：2022-09-26

测试结束时间：2022-09-28

测试人：

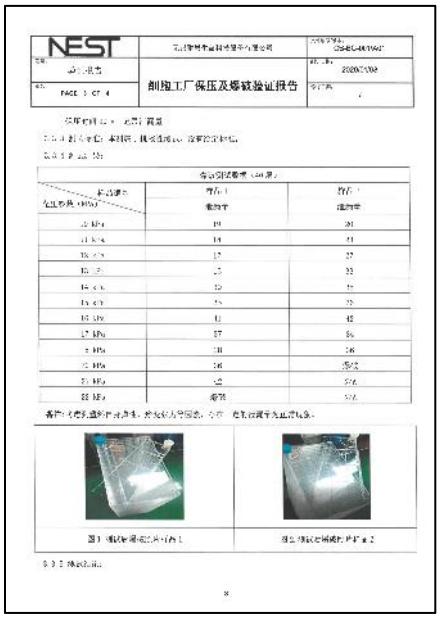
审核人：

细胞工厂保压及爆破验证报告

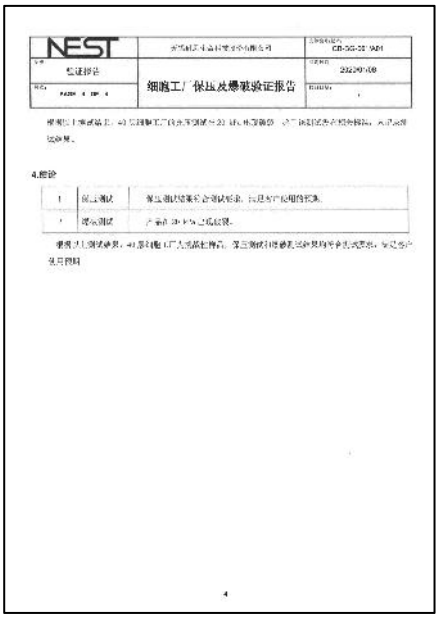
1. 目的

2. 样品

3. 测试



细胞工厂保压及爆破验证报告



细胞工厂保压及爆破验证报告

4. 结论

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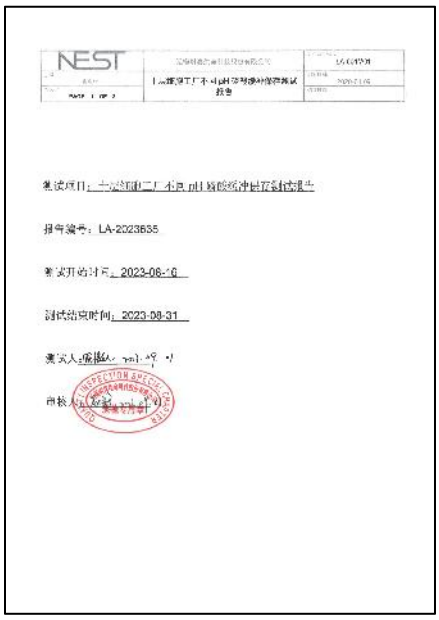
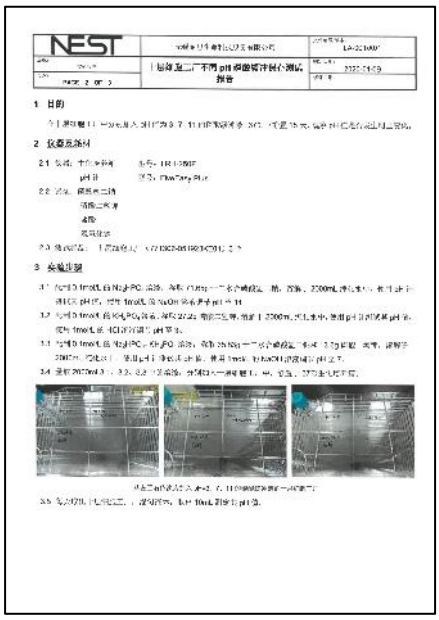
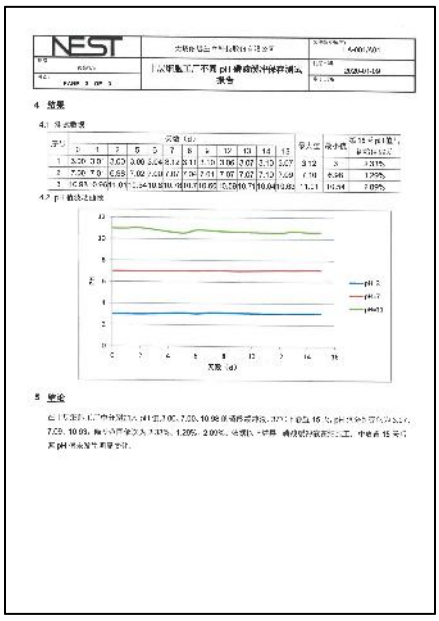
3-5 PH Stability Test Report







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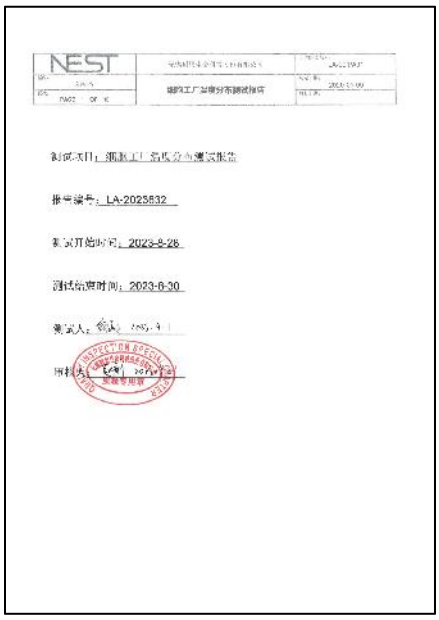
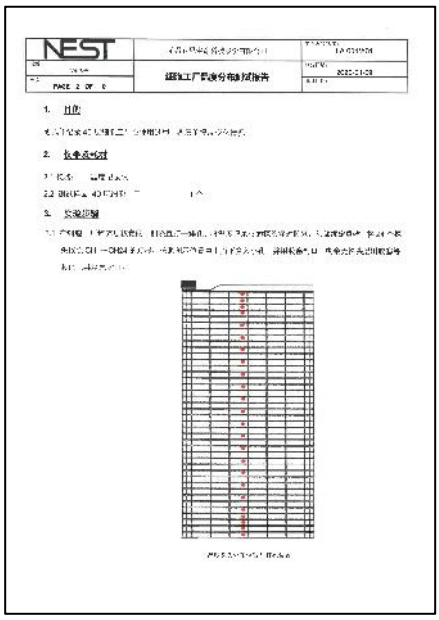
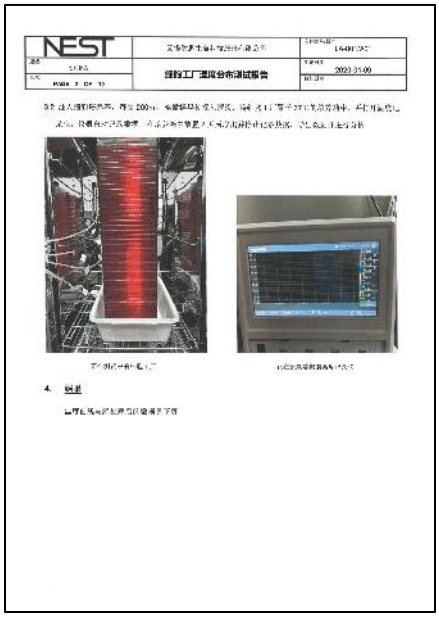
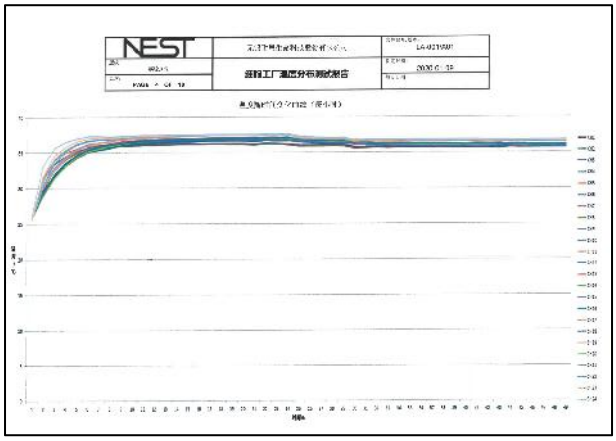
3-6 Temperature Distribution Report









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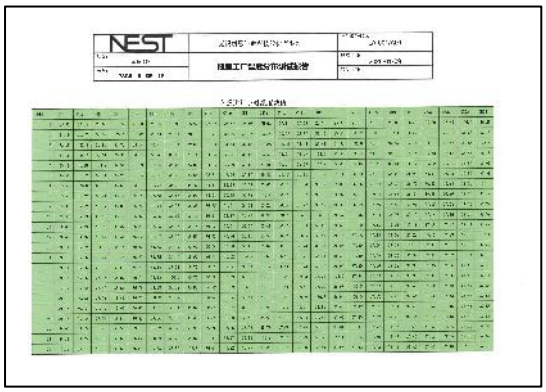

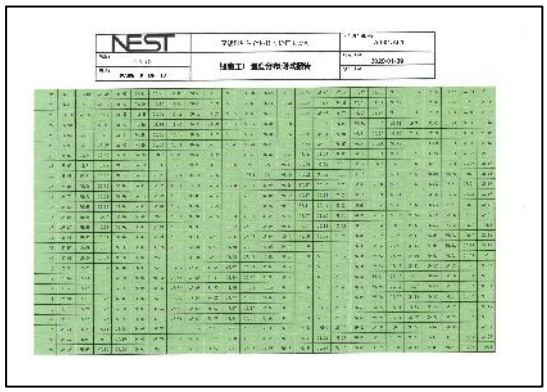

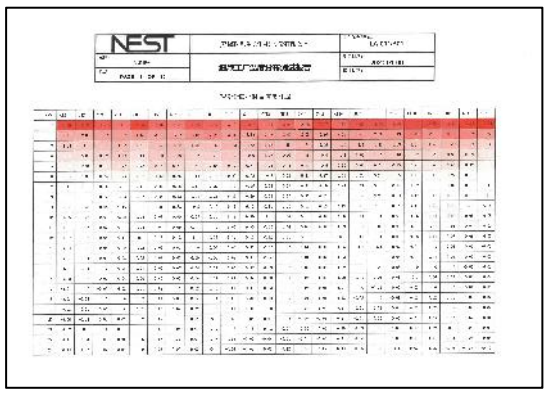

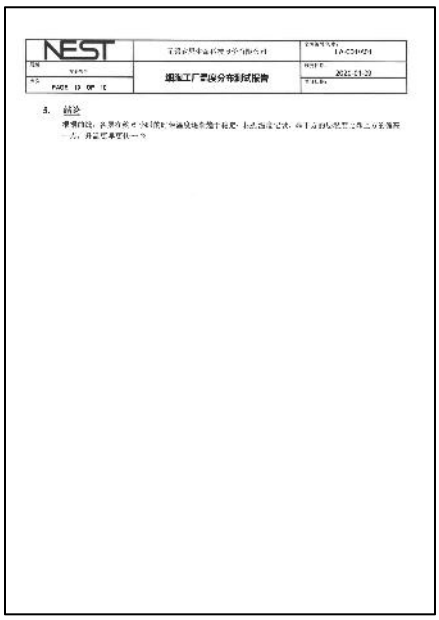

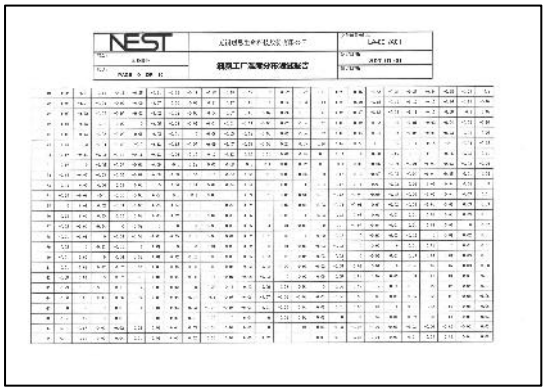

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Annex I

Attachment-1 ISO9001

Certificate

Standard ISO 9001:2015

Certificate Registr. No. 01 100 1832699

Certificate Holder:

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Attachment-2 ISO13485

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2181125-1

Organization: Wuxi NEST Biotechnology Co., Ltd.
No 530, Xida Road, New District,
Wuxi,
214112 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable Medical Laboratory Consumables, Disposable Nebulizers, Specimen Collection Swabs

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244414889-200
Effective date: 2022-12-30
Expiry date: 2025-04-17
Issue date: 2022-12-30

TÜV Rheinland LGA Products GmbH Zertifizierstelle TUVRheinland

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

1 / 1

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

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NEST Scientific Co., Ltd. (Yokohama, Japan)
NEST Scientific Europe BV (Netherlands)
NEST Scientific (MENA) FZE (Sharjah, United Arab Emirates)

Attachment-3 ISO13485, ISO11137

中盛认证

质量管理体系认证证书

兹 证 明

无锡福腾辐照科技有限公司

统一社会信用代码：91320213MA1MA3M87W

注册地址：无锡市新吴区梅村锡达路 530 号　　邮编：214112

审核地址：无锡市新吴区梅村锡达路 530 号　　邮编：214112

其质量管理体系经中盛认证有限公司评定符合
GB/T19001-2016/ISO9001:2015 标准

认证范围：

辐照加工服务

证 书 编 号：ZSRZ221095Q2R0S

证书签发日期：2022 年 12 月 15 日

初次获证日期：2022 年 12 月 15 日

证书有效期至：2025 年 12 月 14 日

ISO ZSRZ

证书签发：

中盛认证有限公司 证书专用章

本证书信息可在中国国家认证认可监督管理委员会官方网站(www.cnca.gov.cn)上查询

获证组织必须每年定期接受监督审核并经审核合格后方可继续有效

地址：江苏省徐州市鼓楼区淮海文化科技产业园 A1 座 329

电话：400-100-2602

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

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

Report No.: SH2393501

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

Date, 2023-12-21

Christoph Dicks
Head of Certification/Notified Body

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NEST Scientific (MENA) FZE (Sharjah, United Arab Emirates)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Supplement to Quality System Certificate

No. SUP 089489 0004 Rev. 03

This supplement is only valid in conjunction with the main certificate: **Q8 089489 0003 Rev. 04**

Certificate Holder:
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

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

EN ISO 11137-1:2015 + A2:2019 "Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd 2:2018)"

Audit Report: SH2393501
Dated: 2023-10-10

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

Valid from: 2024-01-05

Christoph Dicks
Head of Certification/Notified Body

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Attachment-4 CE certification: EU MDR

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 109429 0001 Rev. 00

Manufacturer:	**WUXI NEST BIOTECHNOLOGY CO., LTD** NO.530 XIDA Road New District 214000 Wuxi, Jiangsu PEOPLE'S REPUBLIC OF CHINA
SRN Manufacturer:	CN-MF-000002299
Authorized Representative:	SUNGO Europe B.V. Olympisch Stadion 24, 1076DE Amsterdam, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G21 109429 0001 Rev. 00

Report No.:	SH211724MDR01
Valid from:	2021-12-21
Valid until:	2026-12-20

Issue date: 2021-12-21

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD
Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 109429 0001 Rev. 00

Classification:	I
Device Group:	A020199 - SYRINGES, SINGLE-USE - OTHER A1101 - SAMPLE COLLECTION NEUTRAL SWABS
Device Properties:	MDS 1005.2 - Sterilisation by irradiation
The validity of this certificate depends on conditions and/or is limited to the following:	NA

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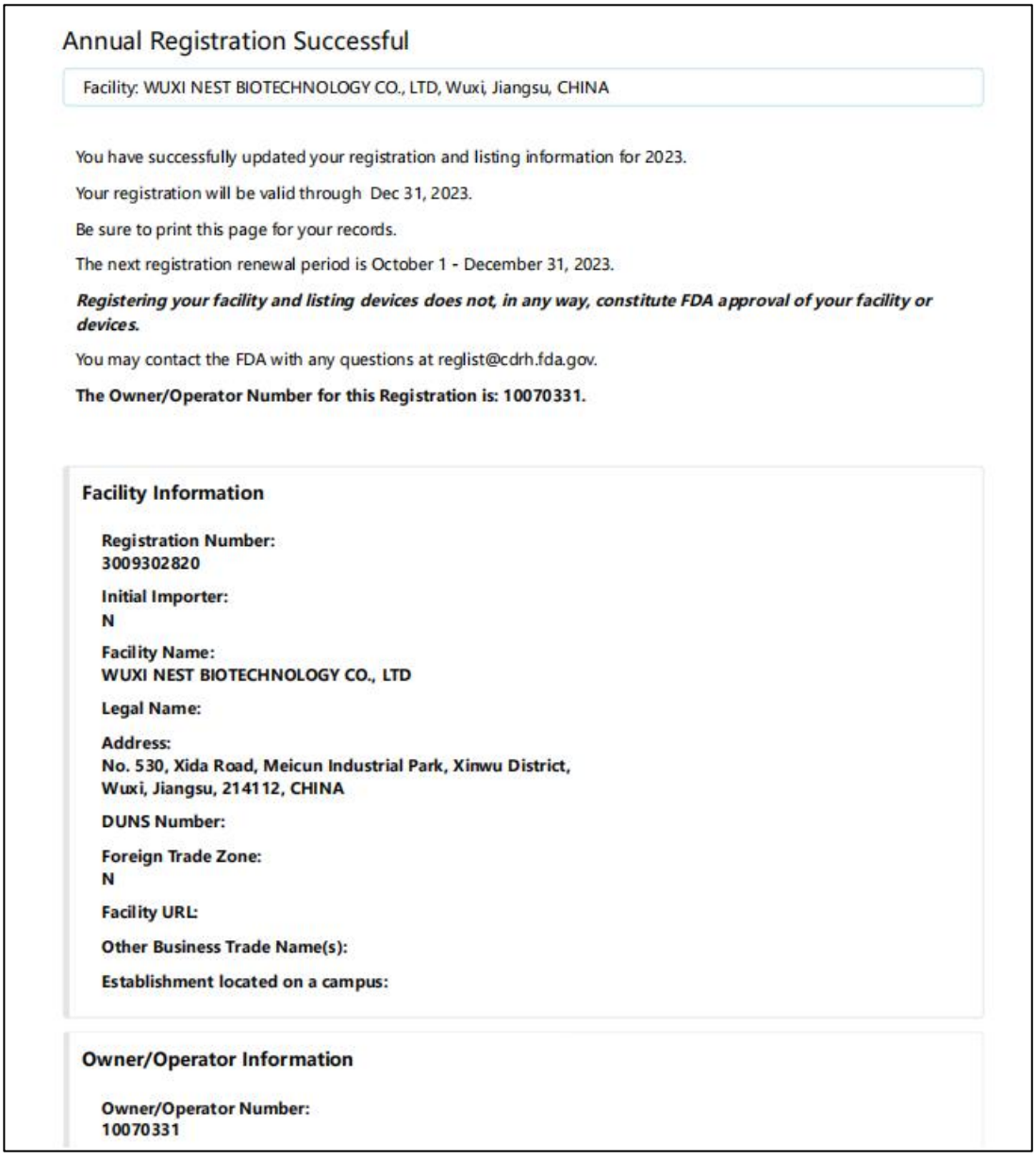
Attachment-5 FDA registration



Annual Registration Successful

Facility: WUXI NEST BIOTECHNOLOGY CO., LTD, Wuxi, Jiangsu, CHINA

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 10070331.

Facility Information

Registration Number:
3009302820

Initial Importer:
N

Facility Name:
WUXI NEST BIOTECHNOLOGY CO., LTD

Legal Name:

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

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
10070331

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Attachment-6 Product List

Product Name	Product Code	Specifications and models
NEST BioFactory	771001	1 layer double wide mouth vent cap
NEST BioFactory	771101	2-layer double wide mouth vent cap
NEST BioFactory	771704	4-layer double wide mouth vent cap
NEST BioFactory	771204	5-layer double wide mouth vent cap
NEST BioFactory	771604	6-layer double wide mouth vent cap
NEST BioFactory	771302	10-layer double wide mouth vent cap
NEST BioFactory	771322	10-layer double wide mouth vent overcap adaptor cap + seal overcap
NEST BioFactory	771503	15-layer double wide mouth vent cap
NEST BioFactory	771403	40-layer double wide mouth vent cap
NEST BioFactory	771403	40-layer double wide mouth vent cap
NEST BioFactory	771422	40-layer double wide mouth vent overcap adaptor cap + sealing overcap
NEST BioFactory	771503	15 layers, double wide mouth, TC treatment
NEST BioFactory	772001	1 layer of double narrow mouth (1 vent cap + 1 seal cap)
NEST BioFactory	772101	2 layers of double narrow mouth (1 vent cap + 1 seal cap)
NEST BioFactory	772704	4 layers of double narrow mouth (1 vent cap + 1 seal cap)
NEST BioFactory	772204	5 layers of double narrow mouth (1 vent cap + 1 seal cap)
NEST BioFactory	772302	10 layers of double narrow mouth (1 vent cap + 1 seal cap)
NEST BioFactory	772403	40-layer double narrow mouth (1 vent cap + 1 seal cap)
NEST BioFactory	773001	1 layer, 1 wide mouth vent cap + 1 narrow mouth seal cap
NEST BioFactory	773101	2 layers, 1 wide mouth vent cap + 1 narrow mouth seal cap
NEST BioFactory	773204	5 layers, 1 wide mouth vent cap + 1 narrow mouth seal cap

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NEST BioFactory	773302	10 layers, 1 wide mouth vent cap + 1 narrow mouth seal cap
NEST BioFactory	773403	40 layers, 1 wide mouth vent cap + 1 narrow mouth seal cap
NEST BioFactory Closed System	774301	10-layer BioFactory (double large mouth) with closed system, TC treatment
NEST BioFactory Accessories	740001	seal cap
NEST BioFactory Accessories	740011	vent cap
NEST BioFactory Accessories	740101	narrow mouth seal cap
NEST BioFactory Accessories	740111	narrow mouth vent cap
NEST BioFactory Accessories	740201	adaptor cap
NEST BioFactory Accessories	740213	adaptor cap pre-installed with vent overcap (cap + vent adaptor cap + vent film)
NEST BioFactory Accessories	740301	filter adaptor cap, NEST green
NEST BioFactory Accessories	740302	filter adaptor cap, original color
NEST BioFactory Accessories	740402	narrow adapter cap, original color
NEST BioFactory Accessories	740913	vent overcap (vent adaptor cap + vent film)
NEST BioFactory Accessories	741001	narrow-mouth adaptor connector
NEST BioFactory Accessories	742001	filter, 0.22μm, pore size 20cm² membrane area
NEST BioFactory Accessories	742011	filter, 0.22μm, pore size 13.8cm² membrane area
NEST BioFactory Accessories	743001	hose clamp
NEST BioFactory	744001	platinum vulcanized tube

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Accessories		
NEST BioFactory Accessories	745001	package (wide to narrow adaptor cap*1, narrow adaptor cap*1, narrow adapter*1, air filter*1, hose clamp*1, hose*15)
NEST BioFactory Accessories	746001	welded pipe
NEST BioFactory Accessories	747001	CPC quick connector(3/8)
NEST BioFactory Accessories	747011	CPC connector plug
NEST BioFactory Accessories	749001	T-shaped connector
NEST BioFactory Accessories	750001	funnel, top diameter 60mm, bottom plug diameter 24mm.
NEST BioFactory Accessories	751001	Y-shaped connector
NEST BioFactory Accessories	751101	bracket

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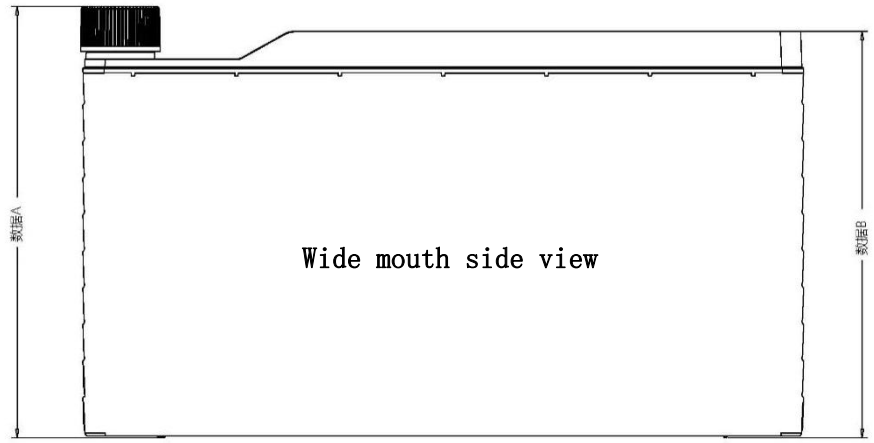
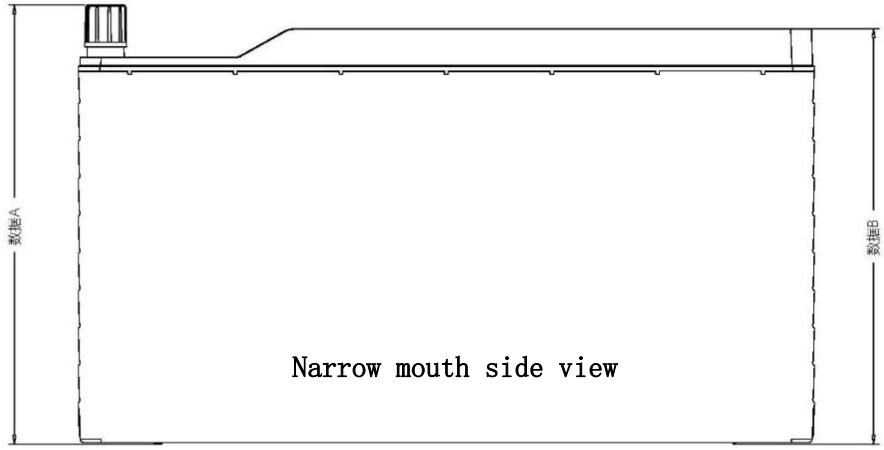
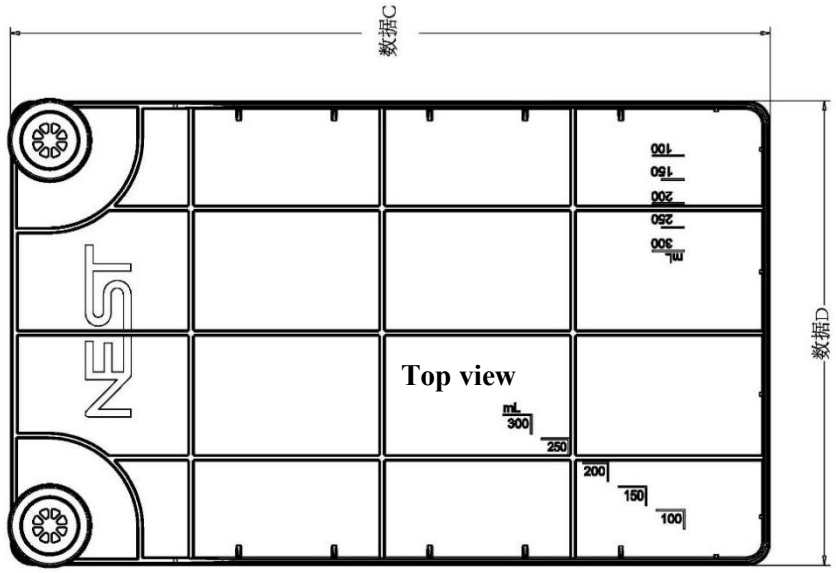
Attachment-7 Product Dimensions Chart







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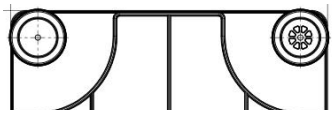
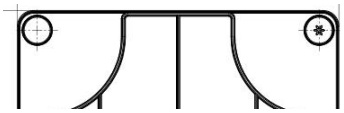
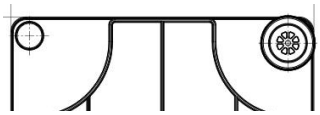
Number of layers	Data A (mm)			Data B (mm)			Data C (mm)	Data D (mm)
Mouth	Double wide mouth	Double narrow mouth	Wide+narrow mouth	Double wide mouth	Double narrow mouth	Wide+narrow mouth		
1	48.00	46.70	48.00	37.40	37.40	37.20	335.00	205.00
2	65.00	63.70	65.00	54.40	54.40	54.30		
4	99.00	97.70	/	88.40	88.40	/		
5	116.00	114.70	116.00	105.40	105.40	105.40		
6	133.00	/	/	/	/	/		
10	201.00	199.70	201.00	190.40	190.40	190.40		
15	286.00	/	/	275.40	/	/		
40	711.00	709.70	711.00	700.40	700.40	700.40		



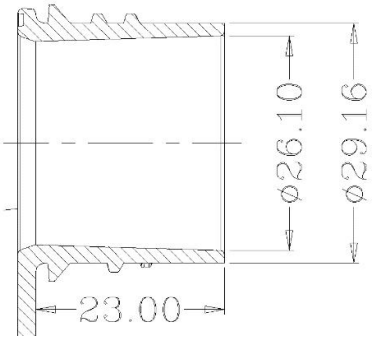
2 Wide Caps



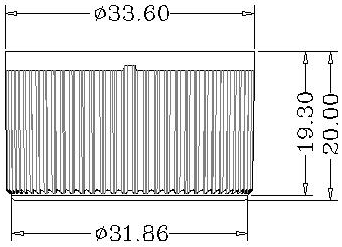
2 Narrow Cap



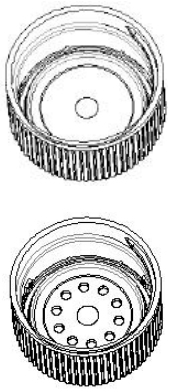
1 Wide Cap & 1 Narrow Cap



Wide mouth

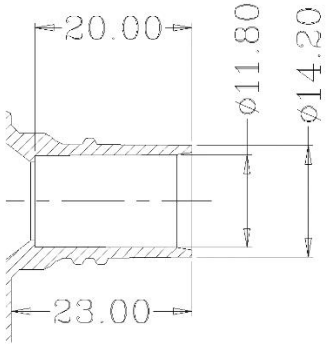


Wide Caps

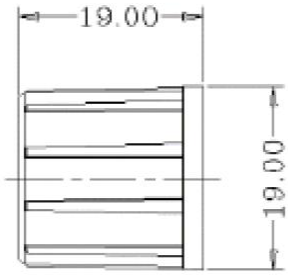


Plug Seal Caps

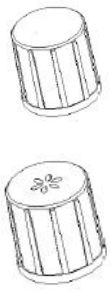
Vent Caps



Narrow mouth



Narrow Caps



Plug Seal Caps

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Attachment -8 COA, COC sample

Wuxi NEST Biotechnology Co., Ltd

Certificate of Analysis

Product Name	10 Chamber BioFactory, 2 Wide Mouth Caps with TPE Tube	Product No.	C71554-BZD080A	Lot No.	091023KE01
DOM	2023-09-10	Expiration Date		2026-08	

No.	Item	Inspection items/basis	Result
1	Appearance	Visual inspection shows no pressure marks, scratches, cracks, etc	Pass
		After welding, the product is free of movable foreign pollutants	Pass
		No obvious weld marks	Pass
		Key nodes are fixed with ties, with good firmness and no detachment	Pass
2	Sealing test	Air leakage tester, no air leakage is qualified	Pass
3	Hydrophilicity test	After TC treatment, the contact Angle does not exceed 39 degrees	Pass
4	Packaging	Correct packaging materials and quantity; intact packaging	Pass
5	Sterilization	Red colored irrediration tag with Certificate of Irradiation	Pass
6	Sterility testing	No microorganisms can be detected	Pass
7	insoluble particles	Pollution index N≤150/ piece	Pass
8	Endotoxin Detection	≤0.05EU/ml	Pass
9	Cell culture test	Cells are evenly distributed and in good condition	Pass
10	Rnase test	No Rnase detected	Pass
11	Dnase test	No Dnase detected	Pass
Conclusion		Pass	

Note: Only Pass or No pass is applicable in filling in 'Result'.

Add: No. 530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi, Jiangsu, China	Tested by	Zhu yunxia	Approved by	He yun
Tel: (+86) 0510-88550090				
Fax: (+86) 0510-88550105	Date	2023-09-17	Date	2023-09-17
https://www.cell-nest.com				

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WUXI NEST BIOTECHNOLOGY CO.,LTD

Certificate of Compliance

Certified EN ISO13485: 2016

Product Number:	C71554-BZD080A	Lot Number:	091023KE01
Product Name:	Nest BioFactory 10 Chamber, double mouth, with tubing, TC, Sterile		
Manufacture Date:	2023-09-10	Expiration Date:	2026-08

Materials:
Virgin Polystyrene, meets USP, Class VI requirements for plastic containers.

Sterilization:
Products certified sterile have been validated for the proper E-Beam radiation dosage based on IS0 11137. This validation procedure is verified to insure all sterilized product receives adequate doses of E-Beam. Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Non-Pyrogenic:
Products certified non-pyrogenic have been tested and have met the criteria established in the *Pharmacopoeia of China* (Ch.P). The acceptance level for product is ≤ 0.05 EU/ml.

Cell Attachment and Growth Characteristics:
The product has been tested for the attribute of Cell Attachment and Growth utilizing an attachment-dependent mammalian cell line in a serum supplemented media, Attachment and Growth Performance.

RNase/DNase Testing:
The product has been tested and is free of any detectable RNase/DNase contamination.

Quality Control Testing:
Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Test:	**Results:**
Visual Attributes:	Pass
Hydrophilic Test:	Pass
Leak Test:	Pass

质检专用章

Drawn:	Zhuyunxia	Approved:	Zhangqin	Released:	Heyun
Date:	2023-09-17	Date:	2023-09-17	Date:	2023-09-17

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