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.

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Chapter 1 Introduction and Overview

1-1 Company Profile

Leading comprehensive service provider in the field of life sciences

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 6,800m2 of Class 100,000 clean-rooms, 2,700m2 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 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 worldwide markets. With the continuous increase in 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 27,000m2 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, ISO11137, FDA, CE certification, and medical device production licenses. In 2021, NEST added 4,500m2 of Class 100,000 clean-rooms and 1,500m2 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

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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

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

Chinese Branch

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

Mainly serving countries and regions: China

Jiangsu, China R&D and Warehousing Base

Production and Storage Area: 26,888 m²

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: 3300m²

Location: Woodbridge, New Jersey, USA

Warehouse in Phoenix, Arizona, USA

Warehousing area: 4500m²

Location: Phoenix, Arizona, USA

Netherlands Branch

Departments and Functions: Sales, Warehousing

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Location: Rotterdam, Netherlands

Mainly serving European regions

United Arab Emirates Branch

Departments and Functions: Sales, Warehousing

Location: Sharjah, United Arab Emirates

Mainly serving the Middle East and North Africa regions

Japan Branch

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 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 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.

1-2-3 FDA Registration

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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, disposable 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 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 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:

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• 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.

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

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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.

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

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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.

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

1-4-3 Batch Testing

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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

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

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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.

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:

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

• 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.

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

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prevent product contamination. Air transportation is not recommended.

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Chapter 2 NEST Cell Culture Flask

2-1 Introduction

Cell Culture Flasks are specially designed containers for in vitro cell culture. They are used for various cell culture operations, including cell culture and passage. These flasks simulate the in vivo environment, allowing cells to survive, grow, and reproduce while maintaining their structure and function.

Typically, Cell Culture Flasks are made of transparent polymer materials. The surfaces of these flasks are specially treated to promote the growth of different types of cells. They are widely used in research areas such as tissue engineering, cell biology, and biomedicine.

NEST, a leading domestic brand, is known for its high-quality products. Cell Culture Flasks from NEST are made of top-notch polystyrene (PS) and manufactured using ultra-precision molds and fully automated production processes. These flasks are ideal for laboratory cell culture and offer excellent optical properties for easy microscopic observation. The flask surfaces are treated with TC to enhance cell adhesion, providing strong support for research and production in the fields of biopharmaceuticals, vaccines, monoclonal antibodies, and more.

2-2 Overview of Cell Culture Flask Product Line

The NEST Cell Culture Flask product line covered by this report includes the following different specifications:

- Cultivation area sizes: T25, T75, T175, T150, T225, three-layer flask, five-layer flask;
- Cap types: Vent cap and plug seal cap;
- Surface modification treatments: TC treated, non-TC treated;
- Aseptic liquid transfer: T25, T75, T225.

Please see the appendix for specific product numbers and specifications.

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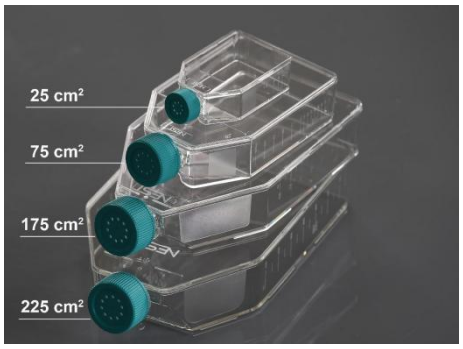
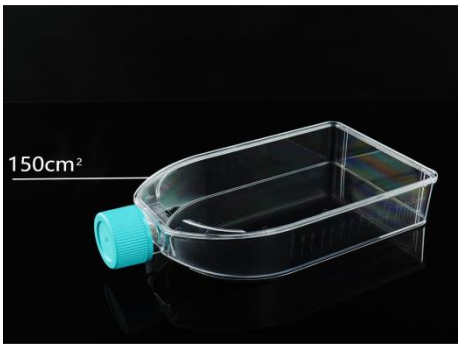
Product photos

Cell Culture Flask



T25/T75/T175/T225



T150

Three-layer flask/five-layer flask

Seal Cap/Vent Cap

Non-tc treated(yellow cap)

Tc treated (green cap)

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Cell Culture Flask Closed System Solution

T25/T75/T225

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2-3 Product Parameters

Product name	Cell Culture Flask
Material	Body: Polystyrene (PS), USP Class VI compliant Cap: Polypropylene (PP), USP Class VI compliant
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	5 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	Referenc USP<788>and "Chinese Pharmacopoeia", insoluble particle test method,≤ 25particles/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.
Production environment and raw materials	Production in a class 10,000 clean environment, raw materials comply with USP Class VI standards.
Hydrophilicity	1. Use a steam atomizer to spray water vapor on the treated surface of the TC product, causing water vapor to condense into fish scale-like flakes. 2. Take 3 droplets of water on the treated surface of the TC product and measure the contact angle. The angle should not exceed 42 degrees.

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Sealing	1. Seal the product with a sealing cover and place it in a sealing tester. Apply a negative pressure of -10Kpa~-9Kpa for 3 minutes. The product should not have any bubbles or water ingress. 2. Pre-fill two-thirds of the product with crystal violet solution and place it flat upside down for 1 hour. The product should not have any leakage.
Design features	1. The bottle neck is elevated, preventing the culture medium from overflowing when placed horizontally, thus reducing the risk of contamination. 2. The unique design of the bottleneck facilitates easy manipulation with a pipette or cell scraper, ensuring thorough cell collection without any dead angles. 3. The bottle body is designed to be stackable, providing stability and ease of storage. 4. The frosted area on the bottle side allows for convenient writing and record-keeping. 5. The sealing cap is specially designed with adjustable positions, allowing for both sealed and open cultivation.
Process features	Ultrasonic welding, without any foreign substances, no addition of any chemicals, eliminating the risk of unknown leachables. TC treatment, conducive to cell adhesion and growth, suitable for large-scale cultivation of adherent cells.

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2-4 Product Raw Materials and Packaging Information

- Cell Culture Flask

PS - Polystyrene (Finished product passed USP VI testing)

PP - Polypropylene (Compliant with USP Class VI)

- Product inner packaging

Co-extruded composite plastic: Compliant with the standards of QB/T 28117-2011

Multi-layer composite plastic: Compliant with the standards of USP<661>, QB/T 1871-1993 and YBB00132002-2015 "General Rules for Medicinal Composite Films and Bags"

2-5 Validation Documents for Cell Culture Flask Components

Please refer to the NEST official website for the relevant validation documents of Cell Culture Flask.

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Chapter 3 Product Testing

3-1 Product Testing Summary

Product Performance Verification Tests	Periodic Monitoring Tests	Batch Release Tests
Hydrophilicity Testing	Sterility Check	Appearance
Sealing Performance Testing	Endotoxin Check	Dimension Control
Cell Culture Testing	Nuclease Testing	Sealing Performance Testing
Biocompatibility and Physicochemical Tests	Cell Culture Testing	Hydrophilicity Testing
Drop and Transportation Testing		
Initial Contaminant Testing		
Shelf Life 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

Hydrophilicity Test:

Select sample product. Visually observe the shape of the water droplets on the TC-treated surface. The water droplets on the TC-treated surface should condense into fish scale-like shapes, meeting the company's standards.

Select sample product. Drop water droplets on the test surface and use a contact angle measuring instrument to measure the contact angle. The angle should not exceed 42 degrees, meeting the company's standards.

Sealing Test:

Single-layer bottle:

Select sample product. Place it in a sealing testing instrument and conduct a continuous negative pressure test. During the test, there should be no bubbles around the bottle and cap, and no water should enter the bottle, meeting the company's standards.

Select sample product. Tighten the breathable cap onto the product and invert it. After the test, there should be no leakage at the bottle cap and film fusion area, meeting the company's standards.

Multi-layer bottle:

Select products before irradiation and use an air pressure tester under the conditions of inflation

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time and inflation pressure. The product should pass the test, meeting the company's standards.

Select products before and after irradiation, tightly screw the sealing cap onto the product, and place it in the sealing testing instrument for a continuous negative pressure test. During the test, there should be no bubbles around the bottle and cap, and no water should enter the bottle, meeting the company's standards.

Cell Culture Test:

Single-layer bottle:

Inoculate Hela cell suspension in logarithmic phase into cell culture bottles of different brands and the same specifications, with 3 bottles for each brand. Randomly select 2 bottles of cells and observe the cell growth and adhesion to the wall and take photographs. Then count the cells in 2 bottles, and for the remaining 1 bottle of cells, stain them with 0.5% crystal violet solution and observe the cell culture status. The cells should adhere to the wall, have uniform growth distribution, excellent uniformity, good condition, cell viability >94%, and amplification factor >6.8 times, with no significant difference from competing brands.

Multi-layer bottle:

Inoculate L-929 cell suspension in logarithmic phase into multi-layer cell culture bottles of different brands and the same specifications, with 2 bottles for each brand. Then observe the cell growth and adhesion to the wall, take photographs, and perform cell digestion counting. The cells should adhere to the wall, have uniform growth distribution, good condition, average cell viability >99%, and average amplification factor >3.3 times, with no significant difference from competing brands.

Inoculate Hela cell suspension in logarithmic phase into multi-layer cell culture bottles. Then stain the cells with 0.5% crystal violet solution and observe the cell distribution status. The cells should have adhered and grown on the wall with uniform distribution, meeting the company's standards.

Biocompatibility and Physicochemical Testing:

Send the product to a third-party testing organization with CNAS, CMA, and ilac-MRA certification.

Refer to the following regulations: USP Class VI (USP<87><88> standard) for the verification of acute toxicity, skin irritation, skin sensitization, in vitro hemolysis, and cytotoxicity to evaluate the biological compatibility, all indicators should meet the regulatory standards.GB/T16886. 11-2021(IS010993-11:2017, IDT); GB/T16886. 10-2017(ISO10993-10:2010, IDT); GB/T16886.4-2022 (ISO 10993-4:2017, IDT); GB/T16886.5-2017 (ISO 10993-5:2009, IDT). Refer to GB/T 14233.1-2008 regulations (USP<665><1665> standard) for the verification of heavy metal content (lead, tin, cadmium, chromium), ignition residue, and leachable substances

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(reducing substances, acid-base properties, UV absorbance, appearance) to evaluate the physicochemical properties, all indicators should meet the regulatory standards.

Drop and Transportation Testing: Performing long-distance transportation and drop tests on the packaged finished products using actual transportation methods. The products and packaging are not damaged during transportation, including during vibrations, handling, and drops.

Initial Contaminant Testing: Conducting a bioburden assessment of the product and controlling the level of initial contaminants according to the relevant standards in ISO 11737-1 and GB/T 19973.1-2015.

Aging Verification Testing:

Select 3 model products and place them in an aging chamber for accelerated aging, with aging periods of 28 days (1-year shelf life), 85 days (3-year shelf life), and 141 days (5-year shelf life). After each aging condition, repeat all the other tests for product performance verification, including biological and physicochemical testing. The test results should meet the company's and regulatory standards.

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.

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 for cell culture flasks, visual inspection is carried out sequentially on the front, top, sides, bottom, and back of the product. The product should have uniform color without any defects such as damage, contamination, deformation, scratches, bubbles, or burrs. The silk-printed and laser-engraved information must be clear, complete, and correctly colored. The product must meet the enterprise standard requirements.

Dimensional Measurement: According to the inspection standards for cell culture bottles, use

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calipers, projectors, height gauges, wall thickness gauges, microbalances, and other equipment for measurement. The product dimensions should be within the standard deviation, meeting the company's standards.

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The following reports are for display purposes only. If you require the original reports, please contact the NEST sales team.

3-2 Hydrophilicity Validation Report

T175 细胞培养瓶亲水性测试验证报告

测试项目：T175 细胞培养瓶亲水性测试验证报告

报告编号：CB-RC-202308096

测试开始时间：2023-08-30

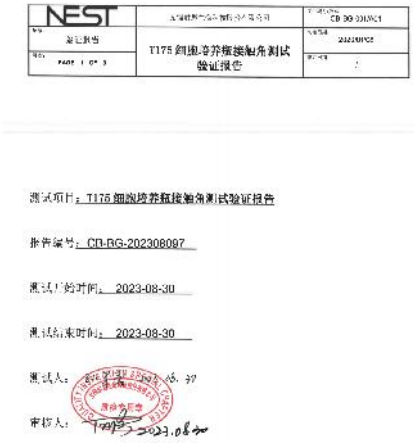
测试结束时间：2023-08-30

测试人：

审核人：

T175 细胞培养瓶亲水性测试验证报告

T175 细胞培养瓶亲水性测试验证报告



T175 细胞培养瓶接触角测试验证报告

测试项目：T175 细胞培养瓶接触角测试验证报告

报告编号：CB-RC-202308097

测试开始时间：2023-08-30

测试结束时间：2023-08-30

测试人：

审核人：

Head Office Email：info@cell-nest.com
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T175 细胞培养瓶接触角测试
验证报告

1. 目的

2. 概述

3. 结论

T175 年限培养瓶接触角测试
验证报告

4. 结论

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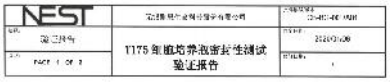
3-3 Sealing Test Report



T175 细胞培养瓶密封性测试验证报告

测试项目：T175 细胞培养瓶密封性测试验证报告

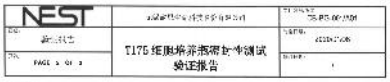
报告编号：CB-BG-202308101

测试开始时间：2023-08-31

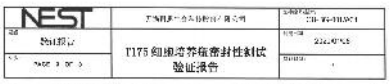
测试结束时间：2023-08-31

测试人：

审核人：



T175 细胞培养瓶密封性测试验证报告



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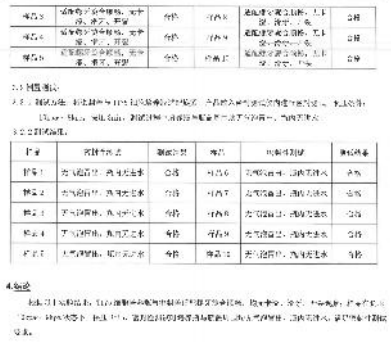

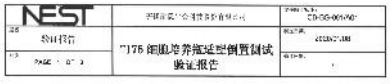

T175 细胞培养瓶竖置倒置测试验证报告

测试项目：T175 细胞培养瓶竖置倒置测试验证报告

报告编号：CB-BG-202308098

测试开始时间：2023-08-30

测试结束时间：2023-08-30

测试人：

审核人：

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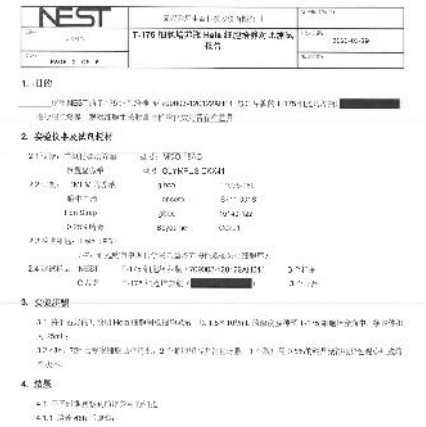
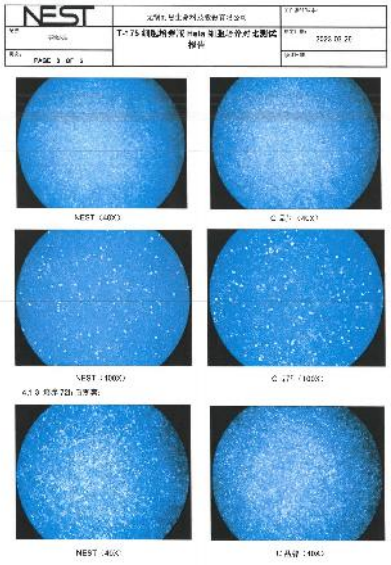
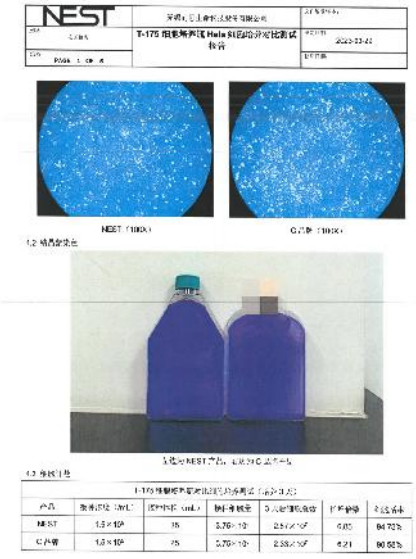
3-4 Cell Culture Test Report







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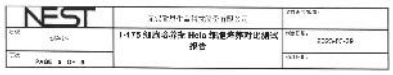

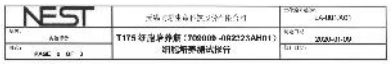

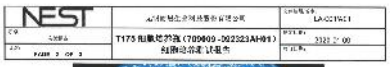

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Annex I

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

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Attachment-2 ISO13485

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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

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

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

1 / 1

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Attachment-3 ISO13485 、 ISO11137

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

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

TÜV SÜD 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

Report No.: SH2393501

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

Date, 2023-12-21

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 1
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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

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

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

Page 1 of 2
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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

Page 2 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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NEST Scientific Europe B.V (Netherlands)
Nest Scientific (MENA) FZE (Sharjah，United Arab Emirates)

Attachment-5 FDA registration

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.

FDA Center for Devices and Radiological Health CDRH CBER

For and on behalf of
SPICA MEDTECH CORP
Authorized Signature(s)

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Attachment-6 Medical Device License

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　至 2029 年 04 月 01 日

发证部门：江苏省药品监督管理局

发证日期：2024 年 04 月 11 日

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Attachment-7 Product List

Product Name	Culture Area(cm^2)	Cat. NO.	Specifications	Packaging
NEST Cell Culture Flask	25	707001	TC, Plug Seal Cap	10 Pcs/Pk, 20 Pks/cs
NEST Cell Culture Flask	25	707003	TC, Vent Cap	10 Pcs/Pk, 20 Pks/cs
NEST Cell Culture Flask	25	707011	Non-treated, Plug Seal Cap	10 Pcs/Pk, 20 Pks/cs
NEST Cell Culture Flask	25	707013	Non-treated, Vent Cap	10 Pcs/Pk, 20 Pks/cs
NEST Cell Culture Flask	75	708001	TC, Plug Seal Cap	5 Pcs/Pk, 20 Pks/cs
NEST Cell Culture Flask	75	708003	TC, Vent Cap	5Pcs/Pk, 20 Pks/cs
NEST Cell Culture Flask	75	708011	Non-treated,Plug Seal Cap	5 Pcs/Pk, 20Pks/cs
NEST Cell Culture Flask	75	708013	Non-treated, Vent Cap	5 Pcs/Pk, 20Pks/cs
NEST Cell Culture Flask	150	720001	TC, Plug Seal Cap	5 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	150	720003	TC, Vent Cap	5 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	150	720011	Non-treated, Plug Seal Cap	5 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	150	720013	Non-treated, Vent Cap	5 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	175	709001	TC, Plug Seal Cap	5 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	175	709003	TC, Vent Cap	5 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	175	709011	Non-treated, Plug Seal Cap	5 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	175	709013	Non-treated, Vent Cap	5 Pcs/Pk, 8 Pks/cs

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NEST Cell Culture Flask	225	721001	TC, Plug Seal Cap	5 Pcs/Pk, 5 Pks/cs
NEST Cell Culture Flask	225	721003	TC, Vent Cap	5 Pcs/Pk, 5 Pks/cs
NEST Cell Culture Flask	225	721011	Non-treated, Plug Seal Cap	5 Pcs/Pk, 5 Pks/cs
NEST Cell Culture Flask	225	721013	Non-treated, Vent Cap	5 Pcs/Pk, 5 Pks/cs
NEST Cell Culture Flask	520	731301	TC, Plug Seal Cap	1 Pcs/Pk, 12 Pks/cs
NEST Cell Culture Flask	520	731302	TC, Vent Cap	1 Pcs/Pk, 12 Pks/cs
NEST Cell Culture Flask	870	731001	Non-treated, Plug Seal Cap	1 Pcs/Pk, 8 Pks/cs
NEST Cell Culture Flask	870	731002	Non-treated, Vent Cap	1 Pcs/Pk, 8 Pks/cs

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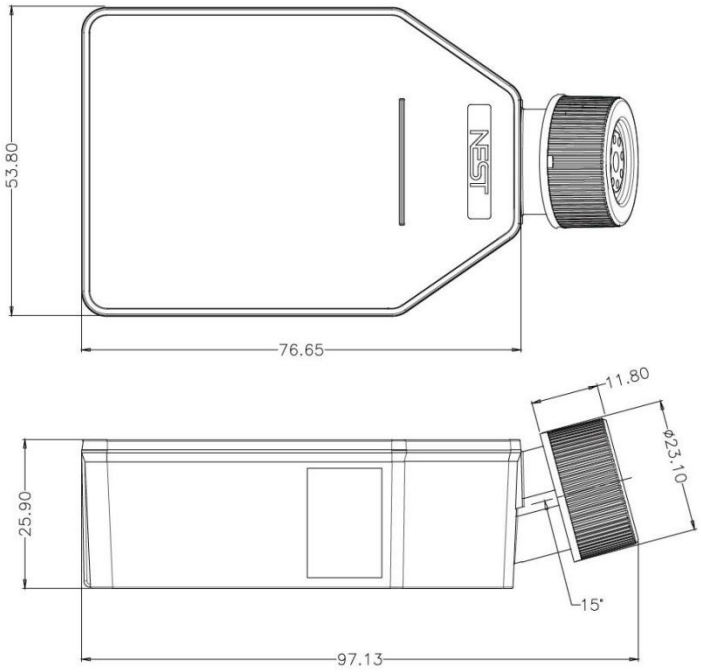
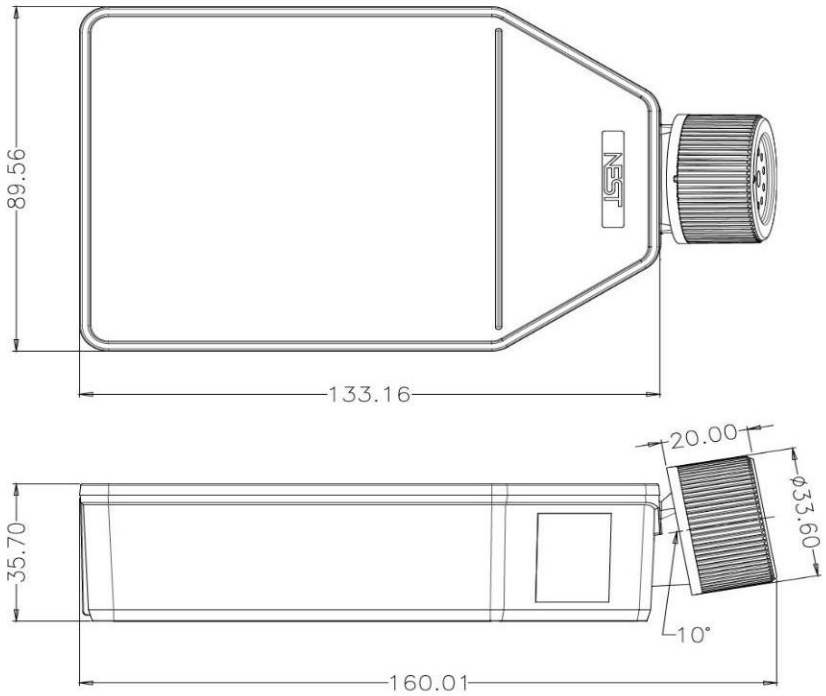
Attachment-8 Product Dimensions Chart



T25 cell culture flask



T75 cell culture flask

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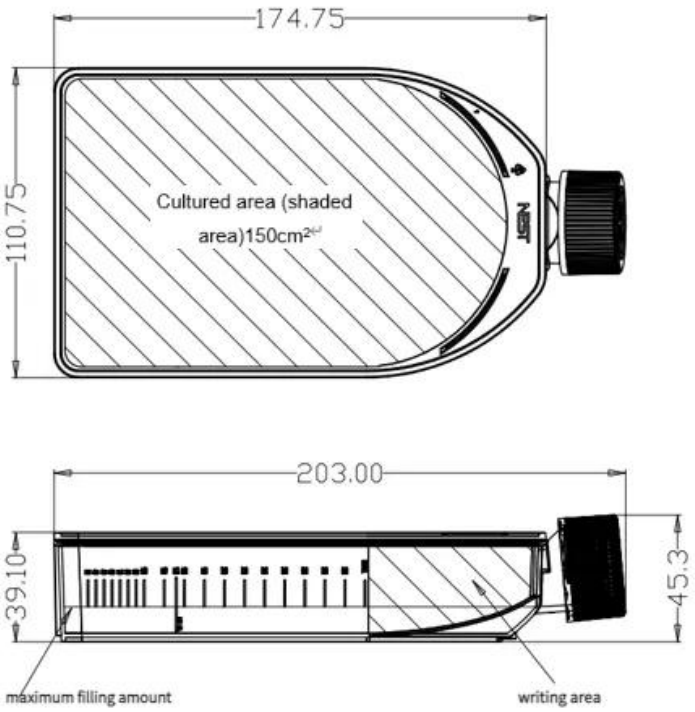
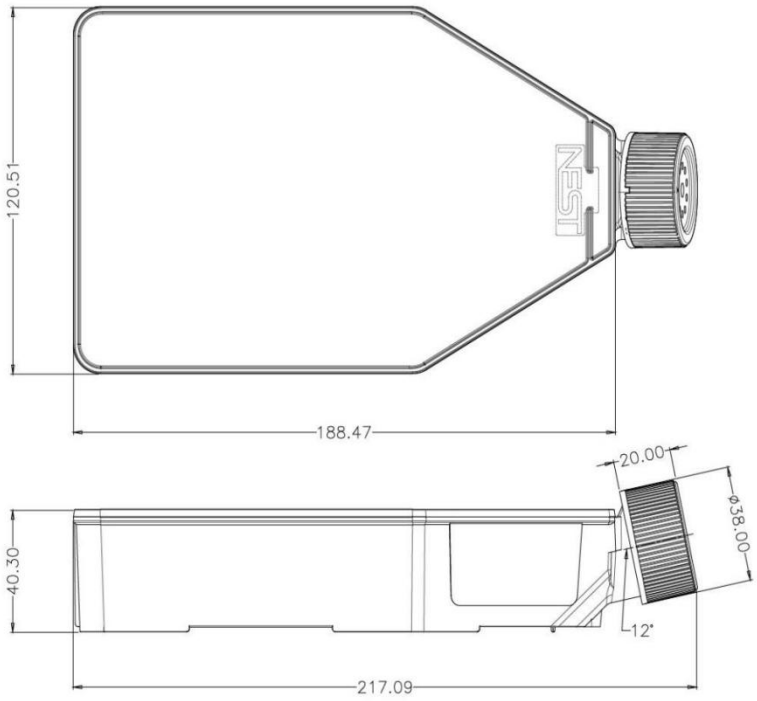


T150 cell culture flask



T175 cell culture flask

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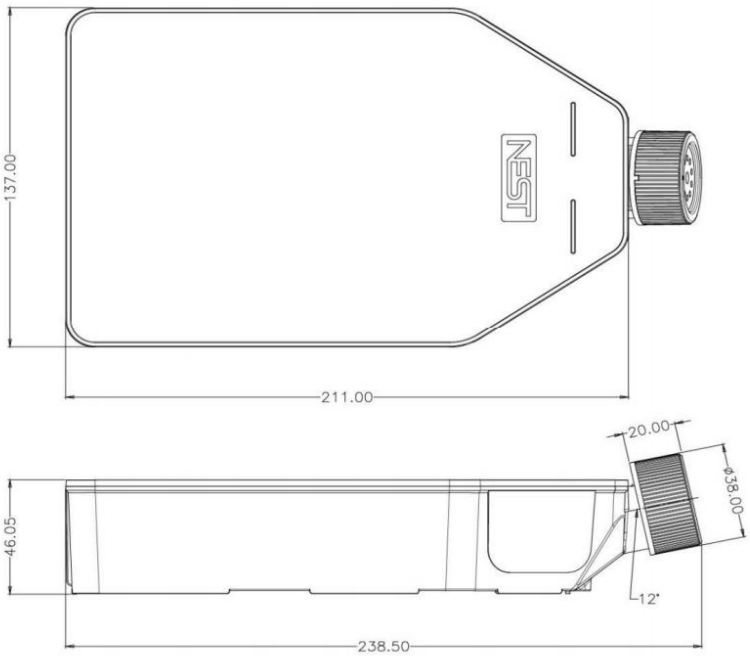
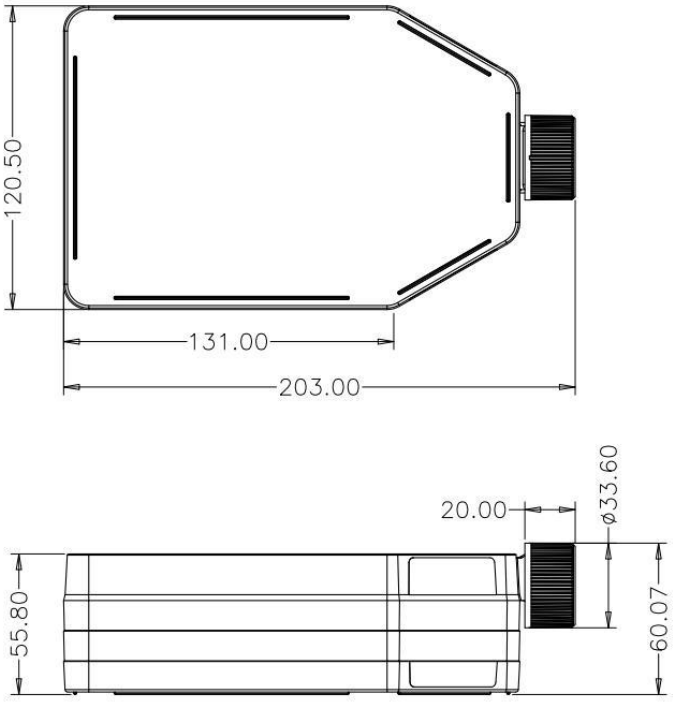


T225 cell culture flask



Three-layer cell culture flask（520cm^2）

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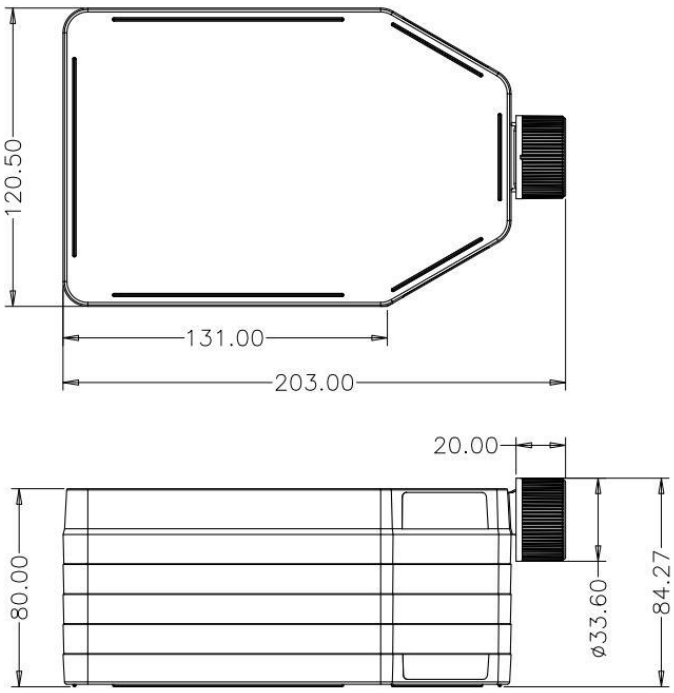

Five-layer cell culture flask（870cm^2）

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Attactment -9 COA sample

Wuxi NEST Biotechnology Co., Ltd

Certificate of Analysis

Product Name	175 cm², Vent Cap, TC	Product No.	709003	Lot No.	110523AH01
DOM	2023-11-05	Expiration Date		2026-10	

No.	Item	Inspection items/basis	Result
1	Appearance	Wire drawing: Wire drawing inside the bottle is not allowed, and wire drawing outside the bottle does not exceed 0.1mm; Flash: Bottle mouth flash is not accepted, other areas flash more than 0.2mm or flash punctures gloves are not accepted; Black spot impurities: The black spot impurities injected into the product are allowed to have one point not exceeding 0.5mm2 on the visible surface, and three points not exceeding 0.2mm2 are acceptable. No more than 4 points of 0.5mm2 in other areas are acceptable; Long rubber mouth: no more than 0.2mm is acceptable, but it is not acceptable if the hand is scratched or the glove is punctures; Bubbles: Allow 1 point on the culture surface that does not exceed 1mm2, and 4 points outside the culture surface that do not exceed 1mm2;	Pass
2	Size	Comforming to the blueprint	Pass
3	Hydrophilicity test	Spray on the product processing surface with a steam meter, and the moisture condenses into fish scales	Pass
4	Contact angle test	After TC treatment, the contact Angle does not exceed 42 degrees	Pass
5	Packaging	Correct packaging materials and quantity; intact packaging	Pass
6	Sterilization	Red colored irrediration tag with Certificate of Irradiation	Pass
7	*Endotoxin Detection	≤0.05EU/ml	Pass
8	*Cell culture test	The cells were evenly distributed and in good condition	Pass
9	*Sterility testing	No microorganisms can be detected	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	2023-11-17	Date	2023-11-17
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