NEST®

Wuxi NEST Biotechnology Co.,Ltd.

Erlenmeyer Flask Validation Binder

Version: 2024 1st Edition

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Online : www.cell-NEST.com

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

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Online : www.cell-NEST.com

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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:

NEST Biotechnology Co., Ltd.

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Online : www.cell-NEST.com

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NEST Scientific Europe BV (Netherlands)
NEST Scientific (MENA) FZE (Sharjah, United Arab Emirates)

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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 27,000m^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 and 1,500m^2 of Class 10,000 clean-rooms for the production of medical devices and

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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

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

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Netherlands Branch

Departments and Functions: Sales, Warehousing

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 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.

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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, 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 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.

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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:

- 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

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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>

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.

1-3-3-4 BPA

NEST has conducted bisphenol A (BPA) testing experiments on PC materials under the ISO17025 system to ensure that the bisphenol A content meets regulatory requirements.

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

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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 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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Chapter2 NEST Erlenmeyer Flasks

2-1 Introduction

NEST Erlenmeyer flask serves as a safer alternative to glass Erlenmeyer flasks. It's ideal for preparing and storing culture media, and works well with various culture techniques. When used in a shaker, it's safer than glass culture bottles. These flasks won't crack, break, or chip during the busy, daily routine of a lab. Lightweight and easy to handle, they contribute to lab safety plans.

NEST Erlenmeyer flasks are made of high-quality polycarbonate (PC) and polyethylene terephthalate-1,4-cyclohexanedimethanol (PETG), which are used in several lab applications. They are dependable and have a low extractables profile.

Both PC and PETG materials provide high transparency, making them ideal for culture flasks. PC Erlenmeyer flasks can be autoclaved, but repeated autoclaving might reduce some mechanical strength. On the other hand, PETG Erlenmeyer flasks are not autoclavable but they are disposable, saving preparation time and reducing the risk of contamination.

NEST offers Erlenmeyer flasks with both flat and baffled bottoms. The baffled bottom improves gas exchange efficiency, ensuring better oxygen dissolution in the culture medium. The cap is made of PP, and both seal cap and vent filter cap options are available. The vent cap's PTFE membrane effectively prevents microorganisms from entering and exiting.

NEST Erlenmeyer flask features clear and accurate scales, making it easy to observe the medium volume. It is recommended to fill the flask with a culture medium that is 30%-40% of the total flask volume.

2-2 Overview of Erlenmeyer Flask Product Line

NEST Erlenmeyer flask product line covered by this report includes the following different specifications：

- Specification I: Material (PETG, PC);
- Specification II: Volumn (125mL, 250mL, 500mL, 1L,2L, 3L);
- Specification III： Cap style (seal cap, vent filter cap);

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- Specification IV: Flat bottom,Baffled bottom;
- Specification V: Packagings

For specific item codes and specifications, please refer to Appendix.

Product image

Erlenmeyer flask

125mL (flat bottom)

250mL (flat bottom)

500mL (flat bottom)

1000mL (flat bottom)

2000mL (flat bottom)

3000mL (flat bottom)

125mL (baffled bottom)

250mL (baffled bottom)

500mL (baffled bottom)

1000mL (baffled bottom)

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Cap

125mL Vent filter cap 781935

250mL Vent filter cap 782935

250mL Seal cap 782925

125mL Seal cap 781925

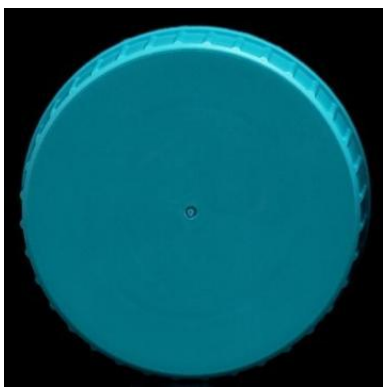
500mL/1000mL Vent filter cap 783935

2L Vent filter cap 785913

2L Seal cap 785903

500mL/1000mL Seal Cap 783925

3L Vent filter cap 786913



3L Seal cap 786903

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2-3 Product Parameters

Product name	Erlenmeyer flask
Material	Body: Polycarbonate(PC), Polyethylene terephthalate-1,4-cyclohexanedimethanol (PETG), USP Class VI compliant Cap: Polypropylene (PP), USP Class VI compliant Gas-permeable membrane: Polytetrafluoroethylene (PTFE), 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 GB/T 19973. 1-2015 and ANSI/AAMI/ISO 11137.
Shelf life	3 years from the date of production (assuming intact packaging)
Endotoxin	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 CHO cells were taken to prepare cell suspensions at suitable concentrations. The cells were inoculated and cultured in a 5% carbon dioxide incubator. During 24h-192h period, the cells were counted and observed every 24h. 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 openings ensure good sealing performance and firmness. Baffled bottom can improve gas exchange efficiency and ensure better oxygen dissolution. 0.22μm PTFE filter cap for pollution-free gas exchange

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	◦ Clear and accurate scale, easy to observe and add liquid
Process features	◦ One-step or integrated injection-pulling-and-blowing process is applied. It does not contain foreign ingredients or added chemicals, eliminating the risk of unknown leaching. One-piece molding improves mechanical strength. ◦ The inner surface has a uniform finish and liquid is not easy to hang on the wall, which is suitable for large-scale culture of suspended cells. ◦ Passed the sealing and pressure test to prevent leakage and is suitable for peristaltic pump pressurization.
Packaging features	Traceable code on the packaging for product traceability. One to three layers packaging to ensure product cleanliness and adaptability to clean environment use.

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2-4 Product Raw Materials and Packaging Information

- Erlenmeyer flask body

PETG/PC - Finished product passed USP VI testing

- Main Components

Vent caps: 781935 782935 783935 785913 786913

Seal caps: 782925 781925 785903 783925 786903

PP - Class USP VI

PTFE- Class USP 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"

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Chapter 3 Product Testing

3-1 Product Testing Summary

Product Performance Verification Tests	Periodic Monitoring Tests	Batch Release Tests
Cell Cultrue Test	Sterility Check	Sealing Performance Test
Shelf Life Validation	Endotoxin Check	Appearance Inspection
High Temperature and High Pressure Test	Nuclease Check	Fitting Test of Cap and Bottle Mouth
Drop and Transportation Test	Cell Cultrue Test	Bottom Flatness and Wall Thickness Testing
Biocompatibility Test		
Leachable Test		
Initial Contaminant Test		

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 Test: Cultivate CHO suspension cells using Erlenmeyer flask . The cells in the flask exhibit normal morphology, even distribution, and good growth status. The cell proliferation rate is within the normal range.

Evaporation Rate Test： The cells were weighed as a whole before culturing, and weighed to calculate the evaporation rate of the Erlenmeyer flask. The test results met the experimental requirements.

Shelf Life Verification: Verify that the samples meet the requirements for tightness and cell culture after accelerated aging, confirming the validity of the packaged products. The experimental conditions are: place PETG/PC Erlenmeyer flasks in an aging incubator, and conduct an aging experiment. According to the standard formula of the shelf life test, the product can be stored at room temperature, after which cell culture and sealing tests are performed separately.The results show that after aging, the products inside the packaging maintain sterility, and the sealing test is qualified. The packaged products can ensure a shelf life of 3 years.

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High Temperature and High Pressure Test: Verify that the sample is valid after being subjected to high temperature and high pressure, in order to test the resistance of the sample to high temperature and high pressure. The experimental conditions were as follows: the flask made of PC material was immersed in a container, washed with pure water, and then placed in a high temperature and pressure container at 121℃, to observe whether defects, deformation and melting occurred. The results show that the shaker made of PC material has good tolerance to high temperature and pressure (this verification only applies to the sample used in this time).

Drop and Transportation Test: Perform 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.

Biocompatibility Test: Conducting USP Class VI verification of the product according to the relevant testing methods in ISO10993, USP<87><88> and GB/T 16886.

Leachable Test: Testing the leachables and extractables of the product according to the standard USP<665><1665> and GB/T14233.1-2008. All items should not exceed the standard detection limit.

Initial Contaminant(Bioburden) 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.

Periodic Monitoring Tests

Sterility Check: After sterilization treatment of the packaged products, conduct 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.

Endotoxin Check: Test 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.

Nuclease Check: The samples will be tested for nuclease 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.

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Batch Release Tests

Tightness Performance Test: According to the inspection standards for the Erlenmeyer flask manufacturing process, the cap and the corresponding bottle are matched and air tightness is tested to control leakage. The test condition is that after matching the Erlenmeyer flask with the vent/seal cap to test its sealing performance. Please refer to the test report for details of the specific test process.

Appearance Inspection: According to the Erlenmeyer flask inspection standards, the appearance of the product is controlled by visual and point gauge measurement. The control points are black spot impurities, burrs, flash edges, bubbles, black spots/oil stains, etc. See Annex COA for specific control standards.

Fitting Test of Cap and Bottle Mouth: According to the inspection standard of the Erlenmeyer flask, test the good fit of the thread and the cap, control the phenomena of being too tight, loose or jammed, and control the product to meet the test requirements.

Bottom Flatness and Wall Thickness Test: According to the inspection standards of the Erlenmeyer flask process, use relevant instruments and methods to control the flatness of bottom and wall thickness of the flask. Place the flask on a horizontal platform and use a level measure to test the bottom surface flatness. The bottle body is stable and does not shake. Use a wall thickness meter to test the wall thickness of the flask and record the minimum and maximum values. The measured value of the thinnest point cannot be lower than the value specified in flask manufacturing process inspection standard.

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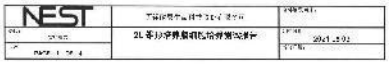
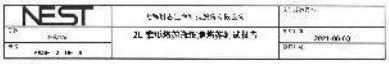
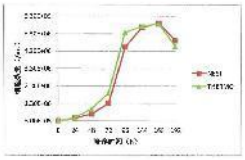
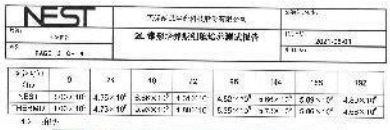
The following reports are for demonstration purposes only. If you require the original reports, please contact a NestBio sales representative.

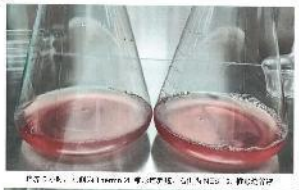
3-2 Cell Culture Test Report

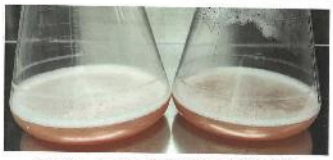












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3-3 Sealing Performance Test Report

PETG 锥形培养瓶
适配性及密封性验证报告

测试项目：PETG 锥形培养瓶适配性及密封性验证报告

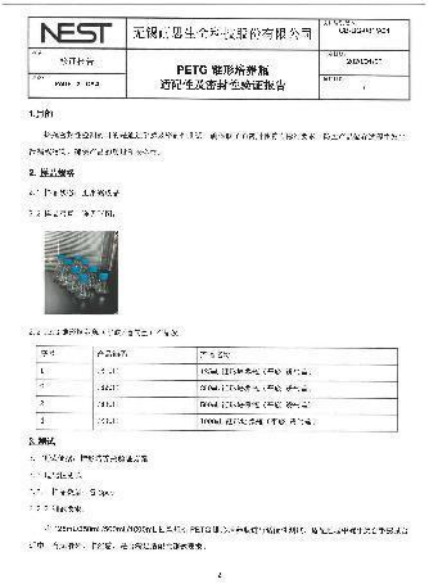
报告编号：CB-RG-20221015

测试开始时间：2022-11-25

测试结束时间：2022-11-25

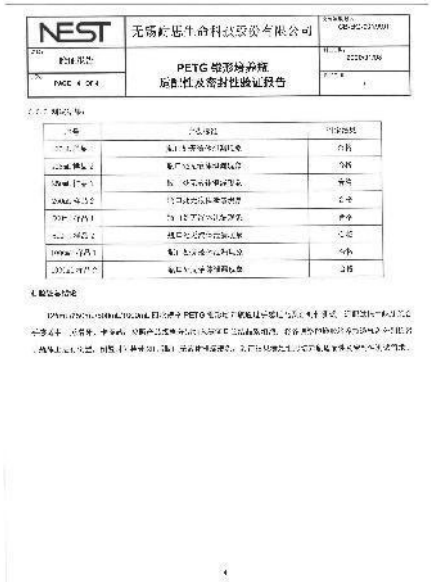
测试人：张慧

审核



PETG 锥形培养瓶
适配性及密封性验证报告

PETG 锥形培养瓶
适配性及密封性验证报告



PETG 锥形培养瓶
适配性及密封性验证报告

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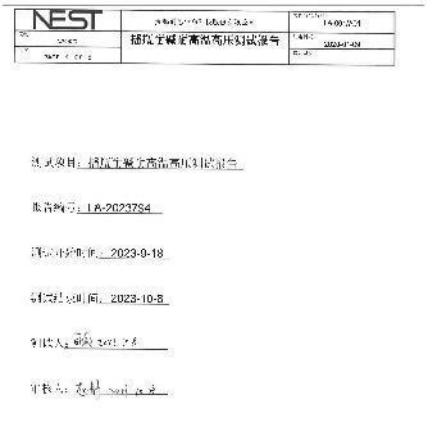
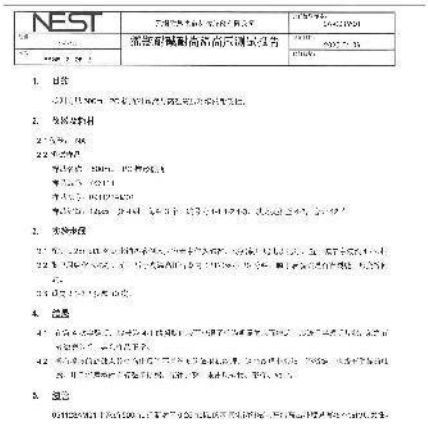
3-4 High Temperature and High Pressure Resistance Test Report





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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

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

TÜV Rheinland LGA Products GmbH Zertifizierstelle

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

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10/020 d 04.06 TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

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Attachment-3 Irradiation Center 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:

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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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
www.zlg.de
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

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-12-21

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

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

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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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)

Head Office Email : info@cell-nest.com
Online : www.cell-NEST.com

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

Attachment-6 Medical Device Production 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

Head Office Email : info@cell-nest.com
Online : www.cell-NEST.com

Overseas NEST USA (New Jersey/Phoenix)
NEST scientific Co., Ltd. (Yokohama, Japan)
NEST Scientific Europe BV (Netherlands)
NEST Scientific (MENA) FZE (Sharjah, United Arab Emirates)

Attachment-7 Product List

Product Name	Product Code	Specifications and models
NEST Erlenmeyer Flask	781101	125 mL Seal cap, flat bottom, PC
NEST Erlenmeyer Flask	781111	125 mL Vent cap, flat bottom, PC
NEST Erlenmeyer Flask	782101	250 mL Seal cap, flat bottom, PC
NEST Erlenmeyer Flask	782111	25 0mL Seal cap,flat bottom, PC
NEST Erlenmeyer Flask	783101	500 mL Seal cap,flat bottom, PC
NEST Erlenmeyer Flask	783111	500 mL Vent cap, flat bottom, PC
NEST Erlenmeyer Flask	784101	1000 mL Seal cap, flat bottom, PC
NEST Erlenmeyer Flask	784111	1000 mL Vent cap, flat bottom, PC
NEST Erlenmeyer Flask	785001	200 0mL Seal cap, flat bottom, PC
NEST Erlenmeyer Flask	785011	2000 mL Vent cap, flat bottom, PC
NEST Erlenmeyer Flask	786001	3000 mL Seal cap, flat bottom, PC
NEST Erlenmeyer Flask	786011	3000 mL Vent cap, flat bottom, PC
NEST Erlenmeyer Flask	781001	125 mL Seal cap, flat bottom, PETG
NEST Erlenmeyer Flask	781011	125 mL Vent cap, flat bottom, PETG
NEST Erlenmeyer Flask	782001	250 mL Seal cap, flat bottom, PETG
NEST Erlenmeyer Flask	782011	250 mL Vent cap, flat bottom, PETG
NEST Erlenmeyer Flask	783001	500 mL Seal cap, flat bottom, PETG
NEST Erlenmeyer Flask	783011	500 mL Vent cap, flat bottom, PETG
NEST Erlenmeyer Flask	784001	1000 mL Seal cap, flat bottom, PETG
NEST Erlenmeyer Flask	784011	1000 mL Seal cap, flat bottom, PETG
NEST Erlenmeyer Flask	781201	125 mL Seal cap, baffled bottom, PC
NEST Erlenmeyer Flask	781211	125 mL Vent cap, baffled bottom, PC
NEST Erlenmeyer Flask	782201	250 mL Seal cap, baffled bottom, PC
NEST Erlenmeyer Flask	782211	250 mL Vent cap, baffled bottom, PC
NEST Erlenmeyer Flask	783201	500 mL Seal cap, baffled bottom, PC
NEST Erlenmeyer Flask	783211	500 mL Vent cap, baffled bottom, PC
NEST Erlenmeyer Flask	784201	1000 mL Seal cap, baffled bottom, PC
NEST Erlenmeyer Flask	784211	1000 mL Seal cap, baffled bottom, PC
NEST Erlenmeyer Flask	781301	125 mL Seal cap, baffled bottom, PETG
NEST Erlenmeyer Flask	781311	125 mL Vent cap, baffled bottom,PETG
NEST Erlenmeyer Flask	782301	250 mL Seal cap, baffled bottom, PETG

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NEST Erlenmeyer Flask	782311	250 mL Vent cap, baffled bottom,PETG
NEST Erlenmeyer Flask	783301	500 mL Seal cap, baffled bottom, PETG
NEST Erlenmeyer Flask	783311	500 mL Vent cap, baffled bottom,PETG
NEST Erlenmeyer Flask	784301	1000 mL Seal cap, baffled bottom, PET
NEST Erlenmeyer Flask	784311	1000 mL Vent cap, baffled bottom,PETG
NEST Erlenmeyer Flask Accessories	781925	125mL Seal cap
NEST Erlenmeyer Flask Accessories	781935	125mL Vent cap
NEST Erlenmeyer Flask Accessories	782925	250mL Seal cap
NEST Erlenmeyer Flask Accessories	782935	250mL Vent cap
NEST Erlenmeyer Flask Accessories	783925	500mL/1000mL Seal cap
NEST Erlenmeyer Flask Accessories	783935	500mL/1000mL Vent cap
NEST Erlenmeyer Flask Accessories	785903	2L Seal cap
NEST Erlenmeyer Flask Accessories	785913	2LVent cap
NEST Erlenmeyer Flask Accessories	786903	3L Seal cap
NEST Erlenmeyer Flask Accessories	786913	3LVent cap

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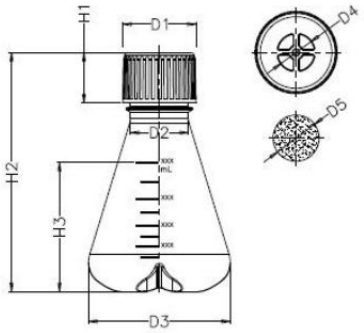
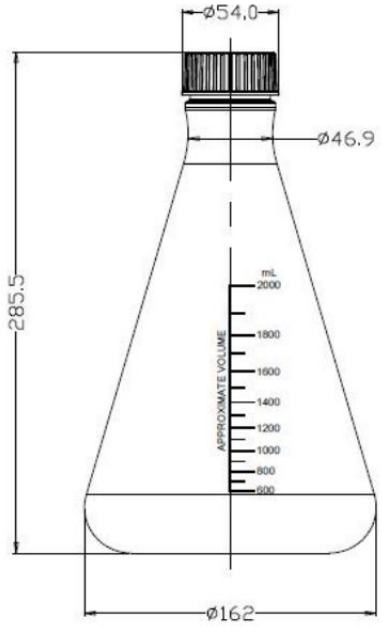
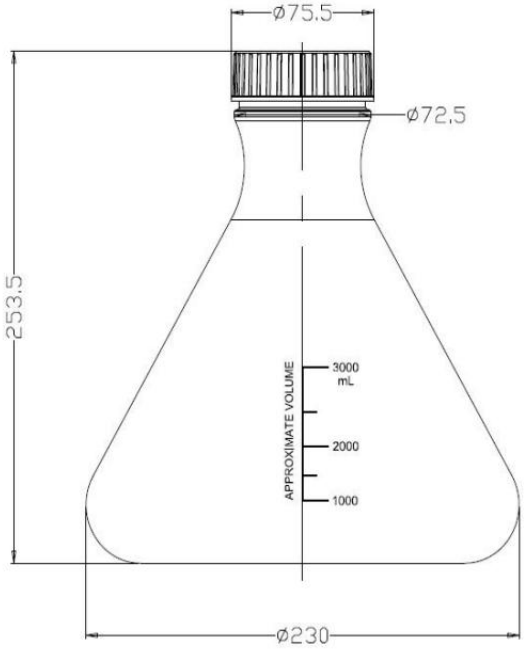
Attachment-8 Product Dimensions Chart



规 格	尺 寸							
	D1	D2	D3	D4	D5	H1	H2	H3
125mL(带挡板)	38.00	29.30	65.60	14.65	22.50	29.50	115.00	59.20
250mL(带挡板)	42.60	34.00	83.00	21.65	27.00	29.50	139.70	73.10
500mL(带挡板)	48.00	39.00	101.00	21.65	27.00	29.50	179.00	104.50
1000mL(带挡板)	48.00	39.00	126.00	21.65	27.00	29.50	207.70	142.40
125mL(平底)	38.00	29.30	65.60	14.65	22.50	29.50	113.00	57.20
250mL(平底)	42.60	34.00	83.00	21.65	27.00	29.50	139.70	73.10
500mL(平底)	48.00	39.00	101.00	21.65	27.00	29.50	176.00	103.50
1000mL(平底)	48.00	39.00	126.00	21.65	27.00	29.50	204.20	138.90





2000ml (平底)3000ml (平底)

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Attachment-9 COA, COC Sample

Wuxi NEST Biotechnology Co., Ltd

Certificate of Analysis

Product Name	3 L, PC, Vent Cap, Flat Bottom	Product No.	786011	Lot No.	011924AQ01
DOM	2024-01-19	Expiration Date		2026-12	

No.	Item	Inspection items/basis	Result
1	Appearance	Black spot: 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. Each point is more than 5cm apart, the bottom area does not exceed 1mm2 points are acceptable, the number of black points at the bottom does not exceed 3. Gate: gate residue ≤0.5mm (bottle mouth, bottle bottom burr can not be scraped) Flaring: Flaring at the cover is not acceptable, and flashing exceeding 0.2mm at other locations is not acceptable. Bubble: The thread area and sealing area are not acceptable, other positions are not more than 0.5mm acceptable. Color dots/unplasticized: Not obvious at a distance of 40cm from the product, allowed.	Pass
2	Size	Comforming to the blueprint	Pass
3	Sealing test	Inverted for 20 minutes, no water seepage	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	*Endotoxin Detection	≤0.05EU/ml	Pass
8	*Cell culture test	The cells were evenly distributed and in good condition	Pass
9	*Rnase test	No Rnase detected	Pass
10	*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	2024-01-29	Date	2024-01-29
https://www.cell-nest.com				

Head Office Email : info@cell-nest.com
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NEST Scientific (MENA) FZE (Sharjah, United Arab Emirates)

WUXI NEST BIOTECHNOLOGY CO.,LTD

Certificate of Compliance

Certified EN ISO13485: 2016

Product Number:	786011		Lot Number	:	011924AQ01
Product Name:	3L Erlenmeyer Flasks, Vent Cap, Sterile				
Manufacture Date	: 2024-01-19		Expiration Date	:	2026-12

Materials:

Polycarbonate, meets USP Class VI requirements and have shown non-toxic according to USP Chapter <88>,"Biological Reactivity Tests, in vivo", Chapter<87>,"Biological reactivity Tests, in Vitro" and/ ISO 10993-5"Tests for in vitro cytotoxicity".

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. All lots are sterilized and certified for proper dosage levels. Products meet a minimum Sterility Assurance Level: (SAL) of 10^{-6}.

BSE/TSE:

Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human andveterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

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

RNase/DNase Free:

Tested by nuclease assay method and found to be free of detectable DNase/RNase 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:

Tests:	Results:
Visual Inspection	Pass
Functional Test	Pass

质检专用章

Drawn:	Zhuyunxia	Approved:	Zhangqin	Released:	Heyun
Date:	2024-01-29	Date:	2024-01-29	Date:	2024-01-29

NEST

TEL:(86)510-88550089/90/91

FAX:(86)510-88550105

No.530, Xida Road, Xinwu District, Wuxi, Jiangsu, China HTTP://WWW.CELL-NEST.COM

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Online : www.cell-NEST.com

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