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Scope and Disclaimer

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

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

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

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

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

Below are our contact details:
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Chapter 1 Introduction and Overview

1-1 Company Profile

Leading comprehensive service provider in the field of life sciences

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

In 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 pharmaceutical packaging consumables.

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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 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 m^2

Location: Wuxi, Jiangsu, China

US Branch

Departments and Functions: Marketing, Sales, Warehousing.

Mainly serving countries and regions: North America, South America

Research and Warehousing Base in Woodbridge, New Jersey, USA

Warehousing area: 3300m^2

Location: Woodbridge, New Jersey, USA

Warehouse in Phoenix, Arizona, USA

Warehousing area: 4500m^2

Location: Phoenix, Arizona, USA

Netherlands 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.

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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 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

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

Production equipment:

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

Testing equipment:

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

1-3-3 Incoming Material Control

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

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

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

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

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

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Test Item	Test Standard
In vitro cytotoxicity test	GB/T 16886.5-2017 / 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.

1-3-4 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

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regulatory requirements for clean-room environments.

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

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

1-3-4-4 Purified Water System Validation

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

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1-4 Product Verification and Quality Control

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

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

1-4-1 Product Performance Validation

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

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

1-4-2 Periodic Monitoring

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

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limited to:

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

1-4-3 Batch Testing

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

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

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1-5 Electron Beam Sterilization and Sterility Assurance

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

1-5-1 ISO 11137

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

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

1-5-2 Bioburden Assessment

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

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

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

1-5-4 Sterile Packaging Validation and Sterility Inspection

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

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

1-6 Supply Chain Stability and Lead Time

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

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

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1-7 Traceability

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

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

1-8 Shelf Life

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

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

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Chapter 2 NEST Cryogenic Tube

2-1 Introduction

Cryogenic tubes, also known as freezing tubes, are essential laboratory consumables widely used in fields such as biology, medicine, and food. They are primarily used to provide a stable low-temperature environment for preserving various types of cells and tissue samples.

Cryogenic tubes are suitable for the preservation of primary cells, passage cells, stem cells, and other types of cells. The cell suspension is added to the cryogenic tube and placed in a low-temperature environment. After long-term storage, the cells retain good viability and proliferative ability. In biomedical research, the low-temperature preservation of tissues is of critical importance. Tissue samples can be cut into small pieces or homogenized into a slurry, mixed with cryopreservation solution, added to the cryogenic tube, and stored in low-temperature conditions to maintain the tissue's original structure and activity.

NEST cryogenic tubes are made from medical-grade polypropylene (PP) and are specially designed to improve freeze resistance and anti-aging performance. They can maintain physical and chemical stability at extremely low temperatures. Additionally, the design of NEST cryogenic tubes takes into account the requirements of low-temperature storage, featuring a soft rubber seal on the water surface, and a one-piece design where the rubber ring and cap are integrated, significantly improving the sealing effect and preventing sample spillage and leakage, ensuring the safety of the sample inside the tube.

As a leading domestic brand, NEST's product quality is widely recognized. Moreover, NEST offers comprehensive solutions for biobank management, supporting the low-temperature storage and information management of various samples during research and production processes. Through NEST cryogenic tubes, you can achieve efficient and controllable biobank management, providing strong support for research and production in the fields of biopharmaceuticals, vaccines, monoclonal antibodies, and more.

2-2 Overview of Cryogenic Tube Product Line

The NEST cryogenic tube product line covered in this report includes the following specifications:

- Standard Cryogenic Tubes:

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External screw cap (1.0mL, 1.5mL, 2.0mL, 4.0mL, 5.0mL)

Internal screw cap (1.5mL, 1.8mL, 4.0mL, 5.0mL)

- QR Code Cryogenic Tubes:

External screw cap (1.5mL, 2.0mL, 4.0mL, 5.0mL)

Internal screw cap (1.5mL, 1.8mL, 4.0mL, 5.0mL)

- Three-in-One Cryogenic Tubes:

External screw cap (0.5mL, 0.75mL, 1.0mL, 2.0mL, 4.0mL, 6.0mL, 8.0mL)

Internal screw cap (0.5mL, 1.0mL)

- Cryogenic Tube Accessories:
- Cryogenic tube color identification: White, Red, Yellow, Blue, Green, Purple
- Standard/QR Code Cryogenic Tube Boxes:

10x10 holes - White panel (1.5mL)

10x10 holes - Green panel (1.8mL/2.0mL)

10x10 holes - Yellow panel (4.0mL)

10x10 holes - Blue panel (5.0mL)

- Three-in-One Cryogenic Tube Boxes:

8x6 holes - SBS (2.0mL)

4x6 holes - SBS (6.0mL)

- Decoding Equipment: Photo box decoder, Multi-box decoding scanner
- Sample Information Management System: NEST Sample Information Management System - 3/5/10/15/20 (corresponding to the number of devices)
- Other: Defrosting machine, Cap tightening machine, Programmed cooling box, Cell recovery device, Ice-free box, Vertical cryogenic rack, Label printer, etc.

Product photos

Standard Cryogenic Tube

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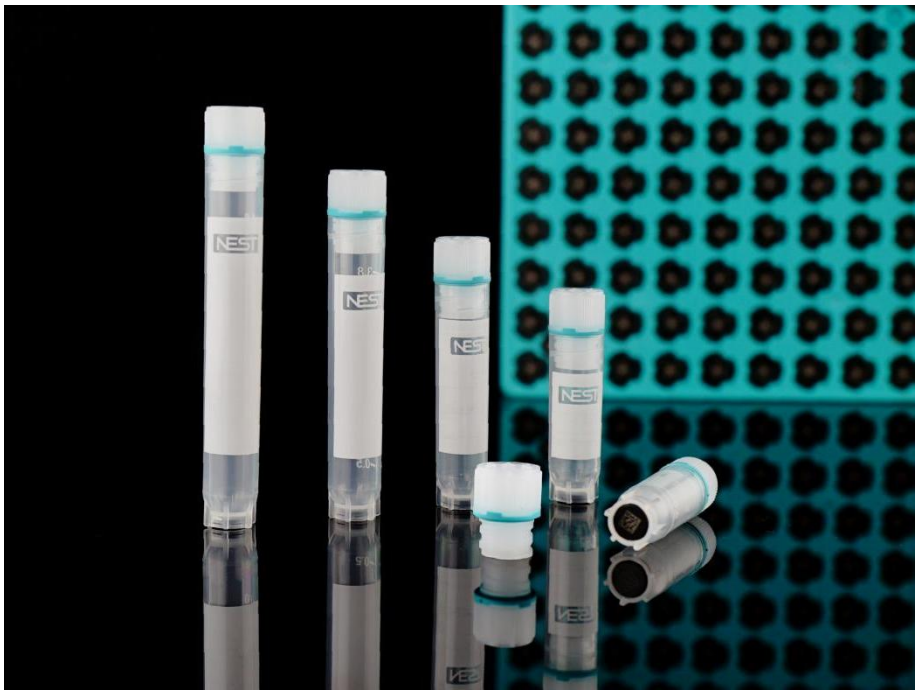
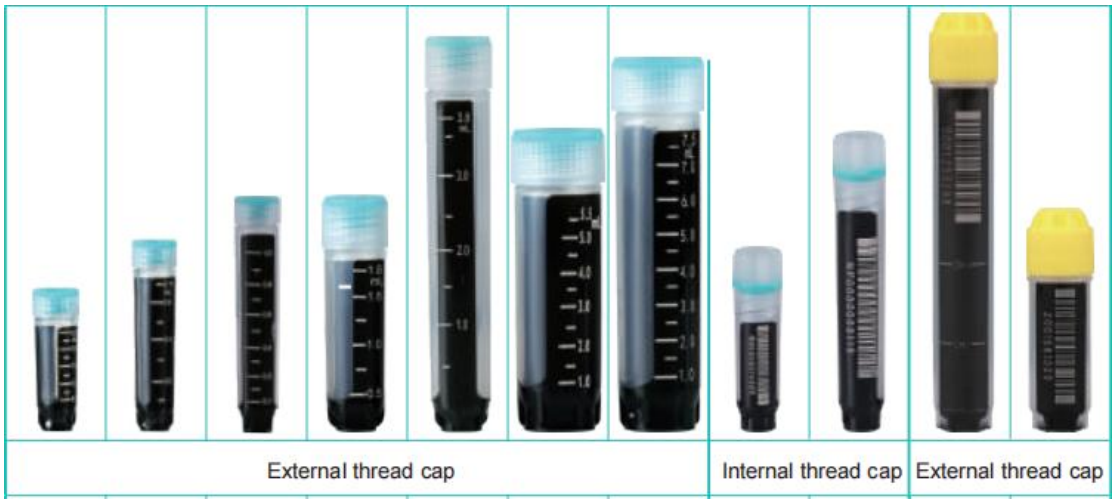
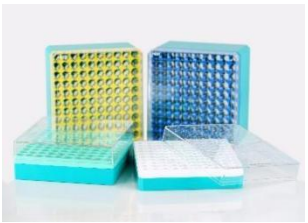
QR Code Cryogenic Tube



Three-in-One Cryogenic Tube



Cryogenic Tube Accessories

Standard Cryogenic Tube color label	Standard/QR code Cryogenic Tube	Three-in-One Cryogenic Tube box
		
White - 611201；	10*10 well（square box）：	SBS（long-square box）：

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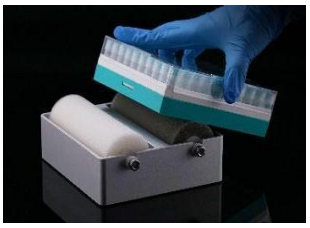
Red - 611202； Yellow - 611203； Blue - 611204； Green - 611205； Purple - 611206。	White- 1.5mL - 616651； Green- 1.8/2.0mL - 616051； Yellow- 4.0mL - 616151； Blue- 5.0mL - 616551。	12*8well-0.5mL external - 616211； 12*8well-1.0mL internal - 616362； 12*8well-1.0mLexternal - 616361； 8*6well- 2.0mL - 616041； 4*6well- 6.0mL - 616841； 4*6well- 8.0mL - 616891；

Decoding Equipment	Sample Information Management System	Defrosting Device
		
Photo box decoder, - NSS nap - 106201 Multi-box decoding scanner - NSS canner - 106202	NEST Sample Information Management System： NSSMS - 20 - 106121； NSSMS - 15 - 106122； NSSMS - 10 - 106123； NSSMS - 5 - 106124； NSSMS - 3 - 106125。	Defrosting Device - 106001； White sponge （ consumbles ） - 106003； Gray sponge （ consumbles ） - 106004。

Cap tightening machine	Programmed cooling box	Cell recovery device
		
Handheld single-channel cryogenic tube cap opener/closer- 106002	Hexagonal Programmable Cooling Box - 200101 Square Programmable Cooling Box - 200102 (Compatible with 1.0/2.0mL	Dual-well dry cell resuscitation - 106007 (Compatible with 2.0mL standard cryogenic tubes)

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standard cryogenic tubes)

Ice-free box	Vertical cryogenic rack	Label printer
		
Ice-free cooling box (empty) - 200901; Ice-free cooling box (with cooling core, 2mL module) - 200103; Cooling core (cold temperature) - 200902; Cooling core (freezing temperature) - 200903; Module (2mL30 wells) - 200904; Module (1.5mL48 wells) - 200905; Module (5mL*30 wells) - 200906; Module (96-well PCR) - 200907;	Cryobox dimensions (133x133x51) mm: Single rack capacity 8 boxes - 200301; Single rack capacity 12 boxes - 200302; Single rack capacity 13 boxes - 200303; Single rack capacity 14 boxes - 200304; Single rack capacity 15 boxes - 200305. Cryobox dimensions (133x133x75) mm: Single rack capacity 6 boxes - 200321; Single rack capacity 8 boxes - 200322; Single rack capacity 9 boxes - 200323; Single rack capacity 10 boxes - 200324. Cryobox dimensions (133x133x98) mm: Single rack capacity 4 boxes - 200341; Single rack capacity 6 boxes - 200342; Single rack capacity 7 boxes - 200343.	Label Printer (Monochrome) - 106006; Cryogenic Liquid Nitrogen Labels (Consumable) - 106091; Ribbon (Consumable) - 106092.

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2-3 Product Parameters

Product name	Standard / QR Code / Three-in-One Cryogenic Tube
Material	Body: Polypropylene (PP), compliant with USP Class VI Cap: Polypropylene (PP), compliant with USP Class VI; Thermoplastic Elastomer (TPE), compliant with US FDA 21 CFR 177.2600
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	Reference USP<788> and "Chinese Pharmacopoeia", insoluble particle test method, ≤ 25 particles/mL for particles ≥10μm, ≤ 3 particles/mL for particles ≥ 25μm.
DNase/RNase-free	Reference USP<1225><1130> and "Chinese Pharmacopoeia", nucleic acid enzyme test method, tested DNase/RNase-Free.
BSE/TSE/GMO	No animal-derived or genetically modified ingredients or tissues, no TSE/BSE/GMO risks.
Cell culture performance	Logarithmic growth phase HeLa, L-929, Vero, MRC-5 cells were taken to prepare cell suspensions at suitable concentrations. The cells were inoculated and cultured in a 5% carbon dioxide incubator. After 48h or 72h, the cells were counted. The proliferation factor, cell attachment, morphology, uniform distribution, and good growth status were observed.
Production environment and raw materials	Produced in a 100,000-class clean environment, workshop environment complies with ISO Class VIII standards.
Low Temperature Tolerance	Cryogenic tubes pre-filled with 80% crystal violet solution, placed in a -80 ° C ultra-low temperature freezer for 5 freeze-thaw cycles, in a -196°C liquid nitrogen tank for 3 freeze-thaw cycles, and in a -196°C

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	liquid nitrogen tank for continuous freezing for 7 days, no cracking or leakage observed after warming.
Sealing	Cryogenic tubes pre-filled with 80% crystal violet solution, placed in a -70Kpa vacuum drying oven for 30 minutes, no leakage observed.
Structural Design Features	1. Special design on the top of the tube cap, compatible with automated capping equipment; 2. Special design of the cap thread structure, smooth capping without jamming; 3. Flat design of the cap and tube body in the longitudinal direction, allowing dense arrangement and increasing the capacity of the cryobox (10*10).
Process Features	1. Dual-color injection molding process ensures stable and reliable sealing performance of the cryotubes; 2. Laser engraving process for QR codes ensures durable, wear-resistant, and corrosion-resistant identification.
Packaging Features	1. 10*10 specification cryobox packaging, with color panel identification for easy distinction; 2. Triple Code Cryotube series all come with SBS specification cryobox packaging, compatible with automated equipment; 3. Bagged specification packaging, reducing the end-user's later usage costs.

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2-4 Product Raw Materials and Packaging Information

- Cryogenic Tube

PP - Polypropylene (finished product passed USP Class VI testing)

Tube Cap Soft Rubber

TPE - Thermoplastic Elastomer (compliant with US FDA 21 CFR 177.2600 standards)

- Product Inner Packaging

Bagged - Multi-layer composite plastic, compliant with QB/T 1871-1993 or USP<661>, YBB00132002-2015 "General Rules for Pharmaceutical Composite Films and Bags" standards;

10*10 Specification Boxed - PC Polycarbonate

SBS Specification Boxed - PP Polypropylene, compliant with USP Class VI

- Other Accessories:

Cryogenic Tube Color Identification: PP, USP Class VI;

Programmable Cooling Box: Aluminum Alloy, EVA;

Defroster: Aluminum Alloy, Sponge;

Vertical Cryogenic Rack: Stainless Steel.

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Chapter 3 Product Testing

3-1 Product Testing Summary

Product Performance Verification Tests	Periodic Monitoring Tests	Batch Release Tests
Temperature Tolerance Testing	Sterility Check	Appearance
Sealing Testing	Endotoxin Check	Dimension Testing
Cell Recovery Rate Testing	Nuclease Testing	Sealing Testing
Printing and Barcode Integrity Testing		Freeze Testing
Biological and Physicochemical Testing		High Temperature Testing
Drop and Transport Testing		
Initial Contaminant Testing		
Accelerated Aging Testing		

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

Product Performance Verification Tests

Temperature Endurance Test: Select three molds of products pre-filled with crystal violet solution, randomly pair the tube caps and bodies, and screw on the caps. After freezing in liquid nitrogen (-196 ° C), remove and thaw in a water bath. No cracking, deformation, bulging, or leakage occurred in the cryogenic tubes, meeting company standards.

Select three molds of products, randomly pair the tube caps and bodies, and screw on the caps. Place the tubes in a vertical autoclave and perform high-temperature sterilization at 121 ° C. No deformation of the cryogenic tube body or cap occurred, meeting company standards.

Select three molds of products pre-filled with crystal violet solution, randomly pair the tube caps and bodies, and screw on the caps. After freezing, remove and thaw in a water bath. No cracking, deformation, bulging, or leakage occurred in the cryogenic tubes, meeting company standards.

Select three molds of products pre-filled with crystal violet solution, randomly pair the tube caps and bodies, and screw on the caps. After freezing in liquid nitrogen (-196°C), remove and thaw in

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a water bath. No cracking, deformation, bulging, or leakage occurred in the cryogenic tubes, meeting company standards.

Sealing Test: Select three molds of products pre-filled with crystal violet solution, randomly pair the tube caps and bodies, and screw on the caps. Place the tubes in a vacuum drying oven and perform a negative pressure test. No leakage occurred in the cryogenic tubes, meeting company standards.

Cell Revival Rate Test: Transfer logarithmic-phase CHO cells, Vero cells, and Hela cells into cryogenic tubes of different brands with the same specifications, with 2 tubes for each cell type. After freezing in liquid nitrogen (-196°C), remove and revive the cells using a dry cell revival instrument. Record the number of cells post-revival. The cell revival rate reached over 98%, surpassing the competing products of the same specifications.

Printing and Barcode Integrity Test: Select three molds of products, use the scale lines as a standard, add purified water (1.00g/mL) corresponding to the capacity, and use a microbalance to weigh the liquid, with an error ≤ 5%, meeting company standards.

Select three molds of products, apply 3M tape to the inked silk print area of the cryogenic tube, and peel off the tape. Repeat the process 3 times. No significant ink peeling (ink attachment area ≥ 95%) occurred, meeting company standards.

Select three molds of cryogenic tubes with a 3-in-1 barcode. Immerse the cryogenic tube completely in a DMSO solution for 5 minutes, then remove and wipe it dry. The laser-engraved surface showed no peeling or blurring. Scan the barcode with a barcode scanner, with a 100% barcode read rate. Randomly select cryogenic tubes, scrape the laser-engraved surface against each other, and scratch the surface with a finger. The laser-engraved surface showed no peeling or blurring. Scan the barcode with a barcode scanner, with a 100% barcode read rate. Apply 3M tape to the laser-engraved surface of the cryogenic tube and peel off the tape. The laser-engraved surface showed no peeling or blurring. Scan the barcode with a barcode scanner, with a 100% barcode read rate. All three tests passed, meeting company standards.

Biological and Physicochemical Testing: The products are sent to third-party testing organizations accredited with CNAS, CMA, and ILAC-MRA certifications.

In accordance with the following regulations, USP Class VI (USP <87> <88> standards), acute toxicity, skin irritation, skin sensitization, in vitro hemolysis, and cytotoxicity biocompatibility validation are performed. All indicators comply with regulatory standards.

GB/T 16886.11-2021 (ISO 10993-11: 2017, IDT); GB/T 16886.10-2017 (ISO 10993-10: 2010, IDT); GB/T 16886.4-2022 (ISO 10993-4: 2017, IDT); GB/T 16886.5-2017 (ISO 10993-5: 2009,

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IDT).

In accordance with GB/T 14233.1-2008 regulations (USP <665> <1665> standards), heavy metal content (lead, tin, cadmium, chromium), ash residue, and leachables (reducing substances, pH, UV absorbance, appearance) are validated. All indicators comply with regulatory standards.

Drop and Transport Testing: Select products, add 1.2 mL of pure water to each tube, and drop freely from 1 meter. Visually inspect for cracks, deformation, or other defects. Place the products under vacuum negative pressure. No leakage occurs, meeting company standards.

Select 1 carton of products and perform drop testing in accordance with GB/T 4857.5-1992 regulations (ISO 2248-1985, EQV). Choose the appropriate drop height and conduct drop tests on 1 corner, 3 edges, and 6 faces of the product packaging. No damage to the cryogenic tubes, and no damage to the packaging bags, meeting regulatory standards.

Select 1 carton of products, pre-fill the cryogenic tubes with crystal violet solution, and perform transport testing based on actual transportation conditions. No damage to the outer carton, no abnormalities in the packaging box, and no cracks or leakage in the cryogenic tubes, meeting company standards.

Initial Contaminant Testing: In accordance with GB/T 19973.1-2015 regulations (ISO 11737-1: 2006, IDT), a bio-burden assessment is conducted to control the initial contaminant level of the product. The results comply with regulatory standards.

Aging Validation Testing: Select three molds of products and place them in an aging chamber (60±2°C) for accelerated aging. The products are placed in the aging chamber for 28 days (1-year shelf life), 85 days (3-year shelf life), and 141 days (5-year shelf life). After each aging condition is completed, biological and physicochemical testing is excluded, and the product performance verification for all other test items is repeated. The test results meet company and regulatory standards.

Periodic Monitoring Tests

Sterility Testing: After sterilization of the packaged products, samples are randomly selected according to the 2020 edition of the Chinese Pharmacopoeia and GB/T 19973.2-2018 (ISO 11737-2: 2019, IDT) for sterility testing. No microbial growth is detected in the test samples, and both positive and negative controls show no abnormalities, meeting regulatory standards.

Endotoxin Testing: In accordance with the 2020 edition of the Chinese Pharmacopoeia and USP <85> standards, samples are randomly selected for testing. The endotoxin content in the test

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samples must be ≤ 0.05 EU/mL, meeting regulatory standards.

Nuclease Testing: In accordance with the 2020 edition of the Chinese Pharmacopoeia and USP <1225> <1130> standards, samples are randomly selected for testing. Using qPCR, the extraction solution from cell culture flasks is amplified. Under the condition that both positive and negative controls show no abnormalities, no DNase or RNase should be detected in the samples, meeting regulatory standards.

Batch Release Tests

Appearance Inspection: According to the cryogenic tube inspection standards, the product is visually inspected sequentially from the front, top, side, bottom, and back. The product has uniform color, with no damage, dirt, deformation, scratches, bubbles, burrs, or other appearance defects. The silk-screen printing and laser-engraved information are clear and complete, with normal color. The product meets company standards.

Dimension Inspection: According to the cryogenic tube inspection standards, the product dimensions are measured using tools such as calipers, projectors, pin gauges, height gauges, and microbalances. All product dimensions are within the standard deviation. The product meets company standards.

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

3-2 Temperature Tolerance Test Report

3-2-1 Cryogenic Tube Freezing Resistance Test Report

测试项目：2.0ml 外旋双封冻存管（三码合一）冷冻耐受报告

报告编号：20221108001

测试开始时间：2022-11-04

测试结束时间：2022-11-06

1. 目的

2. 检验依据

3. 实验仪器

4. 样品准备

5.测试过程

6.结论

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3-2-2 Cryogenic Tube Freeze-Thaw Cycle Verification Report

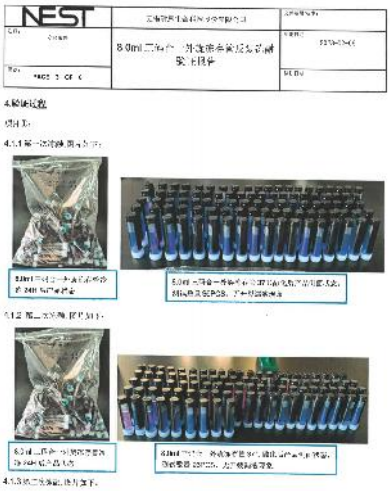
测试项目：8.0ml 一维全一次管冻存管反复冻融验证

报告编号：20230205001

测试开始时间：2023-01-17

测试结束时间：2023-02-04

测试人：



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3-2-3 Cryogenic Box Freeze Resistance Testing Reports

NEST		
	6.0ml SBS	
PAGE 1 OF 2		

6.0ml SBS

CB-BG-20230702[illegible]

2023-07-10

2023-07-13

NEST		
	6.0ml SBS	

1.

FNB143

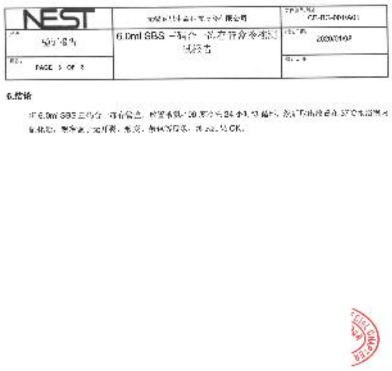
2.

3.

4.

5.

2023/07/10



NEST		
	6.0ml SBS	

6.

6.0ml SBS

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3-2-4 Cryogenic Tubes High Temperature and High Pressure Resistance Testing Reports

测试项目：2.0ml 外旋螺纹冻存管高温灭菌测试报告

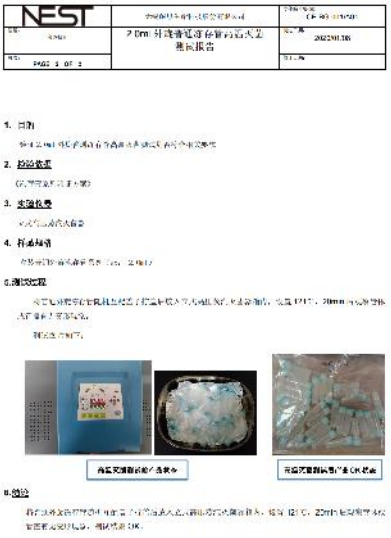
报告编号：CB-BG-202209004

测试开始时间：2022-09-29

测试结束时间：2022-09-29

测试人：

审核人：



1. 目的

2. 检验依据

3. 实验仪器

4. 样品制备

5.测试过程

6.结论

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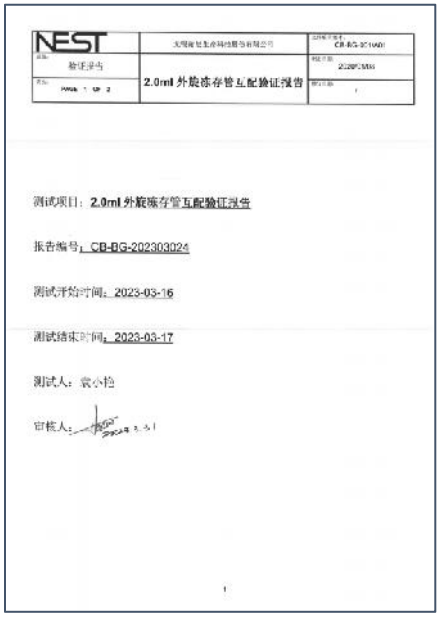
3-3 Sealing Testing Reports



测试项目：2.0ml 外旋冻存管互配验证报告

报告编号：CB-BG-202303024

测试开始时间：2023-03-16

测试结束时间：2023-03-17

测试人：袁小松

审核人：

2.0ml 外旋冻存管互配验证报告

1. 目的

2. 规格

3. 测试

-70Kpa，30min

4. 结论

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Annex I

Attachment-1 ISO9001

Certificate

Standard ISO 9001:2015

Certificate Registr. No. 01 100 1832699

Certificate Holder:

Wuxi NEST Biotechnology Co., Ltd.
Unified Social Credit Code: 91320213685882797G
Registration Address: No. 530, Xida Road, Meicun Industry Zone, Xinwu District, Wuxi, 214112 Jiangsu, P. R. China
Operation Address: same as above

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

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

Validity: The certificate is valid from 2024-10-23 until 2027-10-22.
It remains valid subject to satisfactory surveillance audits.
First certification 2018
This certificate information can be searched on CNCA official website http://www.cnca.gov.cn

2024-09-30

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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

www.tuv.com

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

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Attachment-2 ISO13485

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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

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Attachment-3 ISO13485, ISO11137

中盛认证

质量管理体系认证证书

兹 证 明

无锡福腾辐照科技有限公司

统一社会信用代码：91320213MA1MA3M87W

注册地址：无锡市新吴区梅村锡达路 530 号　　邮编：214112

审核地址：无锡市新吴区梅村锡达路 530 号　　邮编：214112

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

认证范围：

辐照加工服务

证 书 编 号：ZSRZ221095Q2R0S

证书签发日期：2022 年 12 月 15 日

初次获证日期：2022 年 12 月 15 日

证书有效期至：2025 年 12 月 14 日

ISO ZSRZ

证书签发：

中盛认证有限公司 证书专用章

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

获证组织必须每年定期接受监督审核并经审核合格后方可继续有效

地址：江苏省徐州市鼓楼区淮海文化科技产业园 A1 座 329

电话：400-100-2602

Head Office Email : info@cell-nest.com
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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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Page 1 of 1
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Supplement to Quality System Certificate

No. SUP 089489 0004 Rev. 03

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

Certificate Holder:

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

Facility(ies):

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

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

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

Audit Report: SH2393501
Dated: 2023-10-10

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

Valid from: 2024-01-05

Christoph Dicks
Head of Certification/Notified Body

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Attachment-4 CE certification: EU MDR

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

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

Product Service

EU Quality Assurance Certificate (MDR)

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

No. G21 109429 0001 Rev. 00

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

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

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 109429 0001 Rev. 00

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

Issue date: 2021-12-21

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service

EU Quality Assurance Certificate (MDR)

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

No. G21 109429 0001 Rev. 00

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

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Attachment-5 FDA registration

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 CDRH Center for Devices and Radiological Health CBER

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

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Attachment-6 Medical Device Manufacturing 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　　发证部门：江苏省药品监督管理局

至 2029 年 04 月 01 日　　发证日期：2024 年 04 月 11 日

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Attachment-7 Product List

Product name	Package	Code	Specification	Package specification
NEST cryogenic tube	Bag	618901	1.0mL, external	96pcs/bag, 10bag/box
NEST cryogenic tube	Bag	606901	1.5mL, internal	50pcs/bag, 10bag/case, 4case/box
NEST cryogenic tube	Bag	606801	1.5mL, internal	50pcs/bag, 10bag/case, 4case/box
NEST cryogenic tube	Bag	607401	2.0mL, external	50pcs/bag, 10bag/case, 4case/box
NEST cryogenic tube	Bag	607301	1.8mL, internal	50pcs/bag, 10bag/case, 4case/box
NEST cryogenic tube	Bag	608401	4.0mL, external	50pcs/bag, 5bag/case, 4case/box
NEST cryogenic tube	Bag	608301	4.0mL, internal	50pcs/bag, 5bag/case, 4case/box
NEST cryogenic tube	Bag	609401	5.0mL, external	50pcs/bag, 5bag/case, 4case/box
NEST cryogenic tube	Bag	609301	5.0mL, internal	50pcs/bag, 5bag/case, 4case/box
NEST cryogenic tube	Box10*10	606902	1.5mL, external	100pcs/case, 14case/box
NEST cryogenic tube	Box10*10	606802	1.5mL, internal	100pcs/case, 14case/box
NEST cryogenic tube	Box10*10	607402	2.0mL, external	100pcs/case, 14case/box
NEST cryogenic tube	Box10*10	607302	1.8mL, internal	100pcs/case, 12case/box
NEST cryogenic tube	Box10*10	608402	4.0mL, external	100pcs/case, 8case/box
NEST cryogenic tube	Box10*10	608302	4.0mL, internal	100pcs/case, 8case/box
NEST cryogenic tube	Box10*10	609402	5.0mL, external	100pcs/case, 6case/box
NEST cryogenic tube	Box10*10	609302	5.0mL, internal	100pcs/case, 6case/box
NEST cryogenic tube	Box8*12	618906	1.0mL, external	96pcs/case, 10case/box

Product name	Package	Code	Specification	Package specification
NEST cryogenic tube	Box10*10	606952	1.5mL, external	100pcs/case, 14case/box
NEST cryogenic tube	Box10*10	606852	1.5mL, internal	100pcs/case, 14case/box
NEST cryogenic tube	Box10*10	607452	2.0mL, external	100pcs/case, 12case/box
NEST cryogenic tube	Box10*10	607352	1.8mL, internal	100pcs/case, 12case/box
NEST cryogenic tube	Box10*10	608452	4.0mL, external	100pcs/case, 8case/box
NEST cryogenic tube	Box10*10	608352	4.0mL, internal	100pcs/case, 8case/box
NEST cryogenic tube	Box10*10	609452	5.0mL, external	100pcs/case, 6case/box
NEST cryogenic tube	Box10*10	609352	5.0mL, internal	100pcs/case, 6case/box
NEST cryogenic tube	Box6*8	612891	2.0mL, external	48pcs/case, 10case/box
NEST cryogenic tube	Box6*8	614591	4.0mL, external	48pcs/case, 10case/box

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Product name	Package	Code	Specification	Package specification
NEST cryogenic tube	Bag	612541	0.5mL, external	96pcs/bag, 10bag/box
NEST cryogenic tube	Bag	612641	0.75mL, internal	96pcs/bag, 10bag/box
NEST cryogenic tube	Bag	612741	1.0mL, external	96pcs/bag, 10bag/box
NEST cryogenic tube	Bag	612841	2.0mL, external	48pcs/bag, 10bag/box
NEST cryogenic tube	Bag	614541	4.0mL, external	48pcs/bag, 10bag/box
NEST cryogenic tube	Bag	614641	6.0mL, external	24pcs/bag, 10bag/box
NEST cryogenic tube	Bag	614741	8.0mL, external	24pcs/bag, 10bag/box
NEST cryogenic tube	Bag	612521	0.5mL, internal	96pcs/bag, 10bag/box
NEST cryogenic tube	Bag	612721	1.0mL, internal	96pcs/bag, 10bag/box
NEST cryogenic tube	Box8*12	612551	0.5mL, external	96pcs/case, 10case/box
NEST cryogenic tube	Box8*12	612651	0.75mL, external	96pcs/case, 10case/box
NEST cryogenic tube	Box8*12	612751	1.0mL, external	96pcs/case, 10case/box
NEST cryogenic tube	Box6*8	612851	2.0mL, external	48pcs/case, 10case/box
NEST cryogenic tube	Box6*8	614551	4.0mL, external	48pcs/case, 10case/box
NEST cryogenic tube	Box4*6	614651	6.0mL, external	24pcs/case, 10case/box
NEST cryogenic tube	Box4*6	614751	8.0mL, external	24pcs/case, 10case/box
NEST cryogenic tube	Box8*12	612531	0.5mL, internal	96pcs/case, 10case/box
NEST cryogenic tube	Box8*12	612731	1.0mL, internal	96pcs/case, 10case/box

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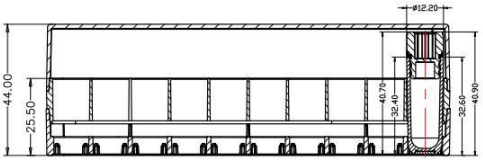
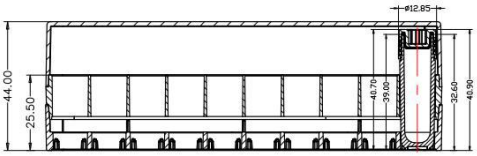
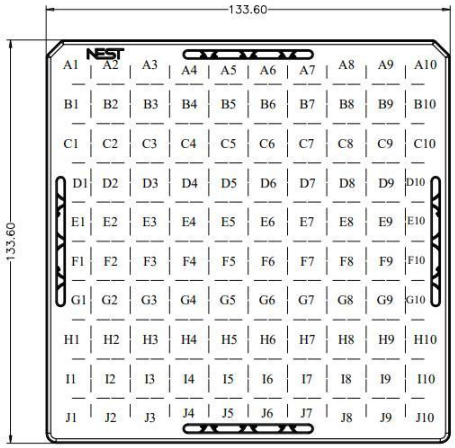
Attachment-8 Product Dimensions Chart







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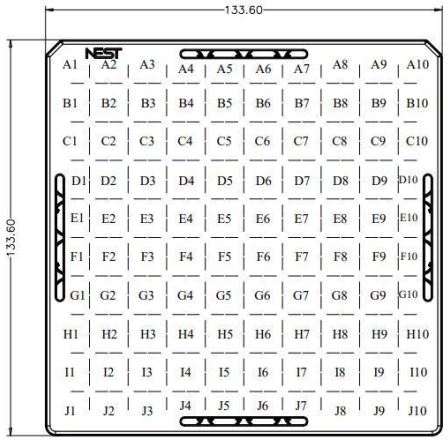

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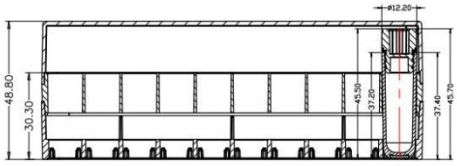

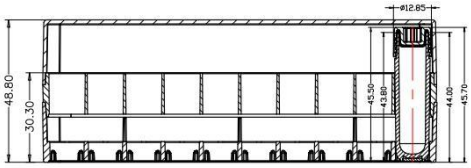

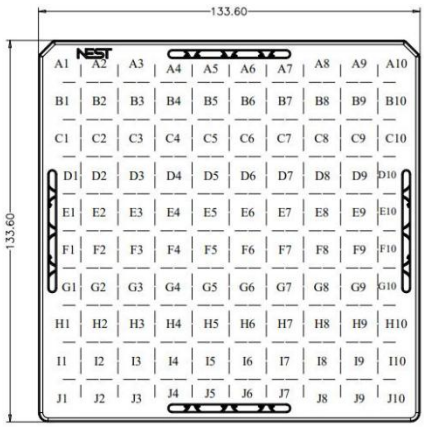

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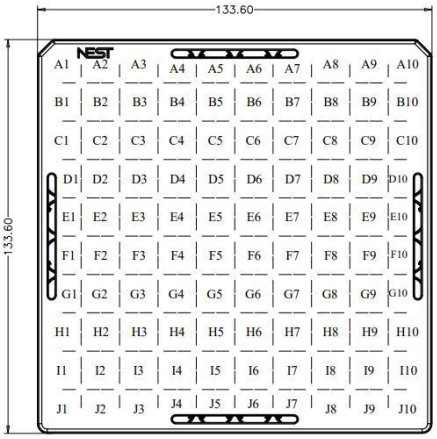

2.0mL external cap

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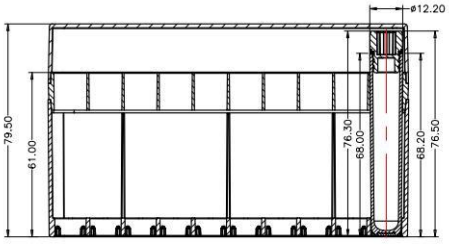

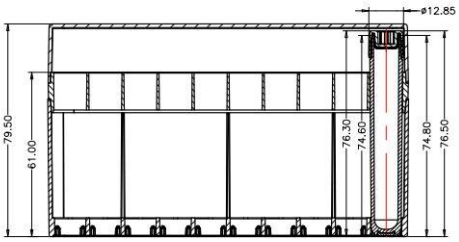

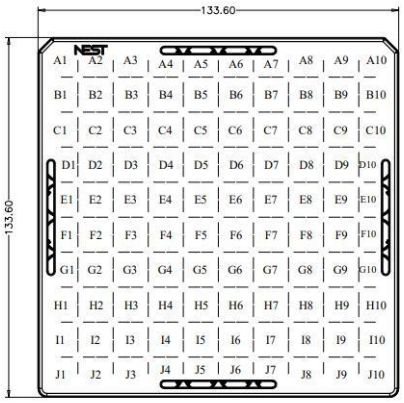

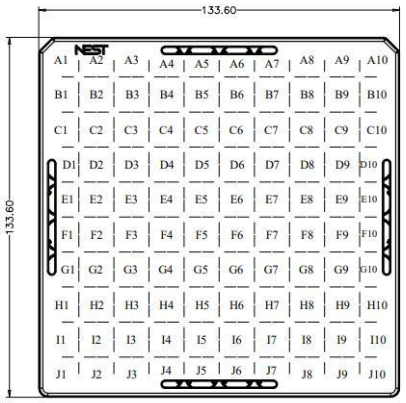

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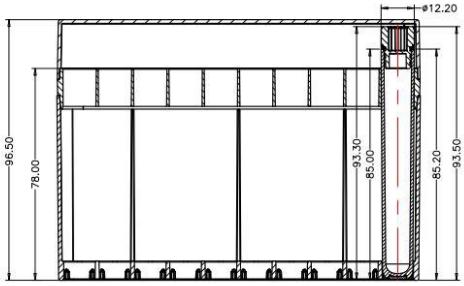
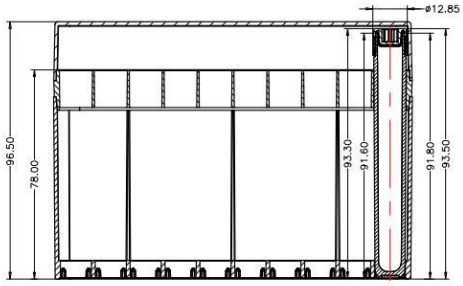
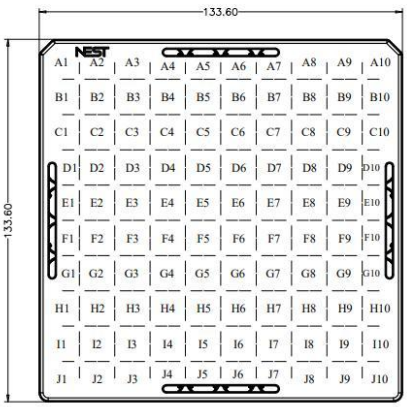
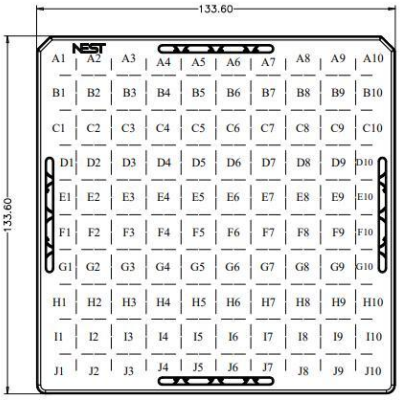
4.0mL external cap









5.0mL internal cap

5.0mL external cap

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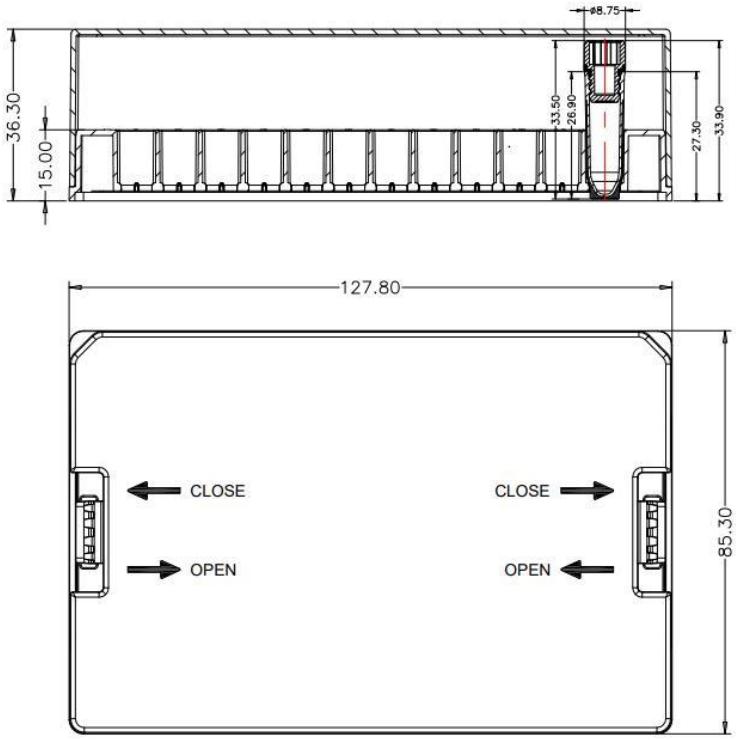

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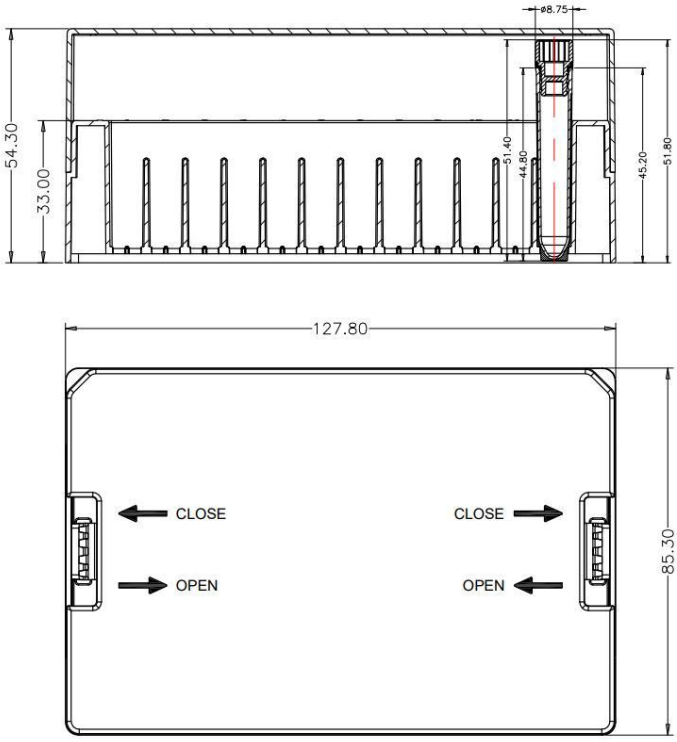

1.0mL internal cap Three-in-One

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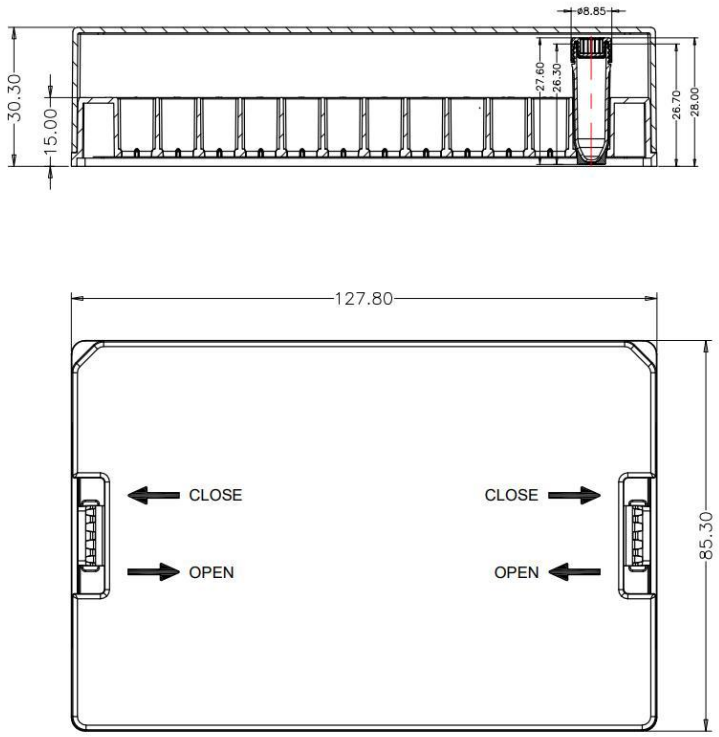

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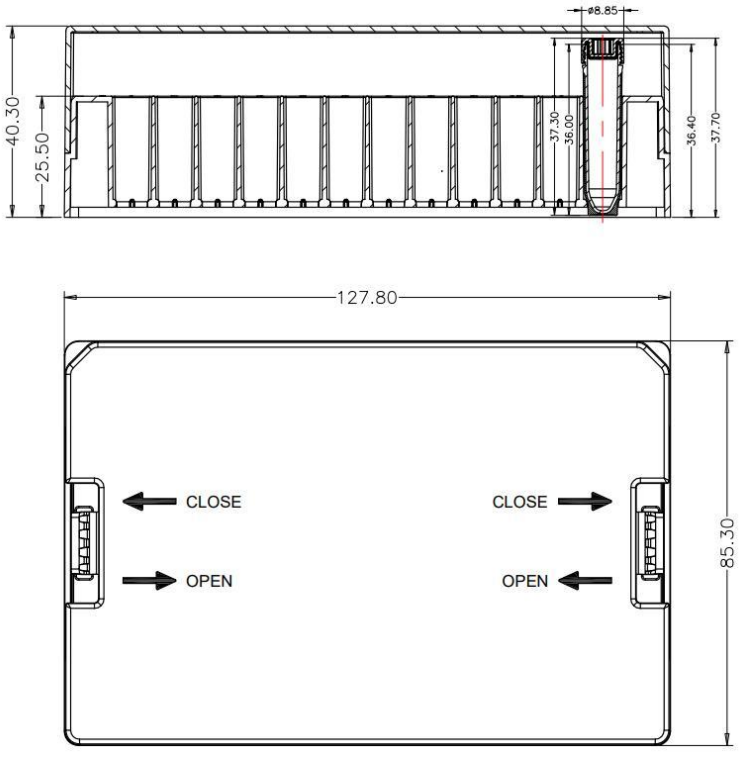

0.75mL external cap Three-in-One

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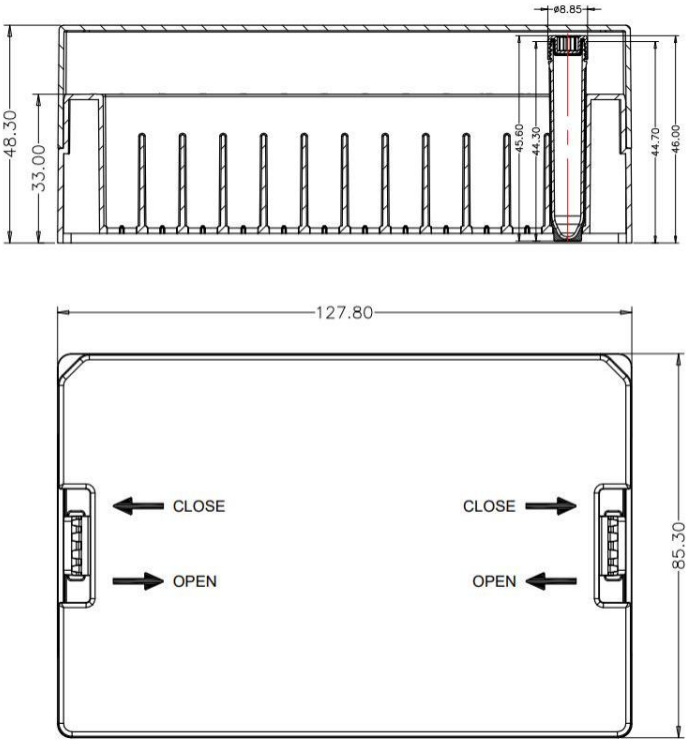
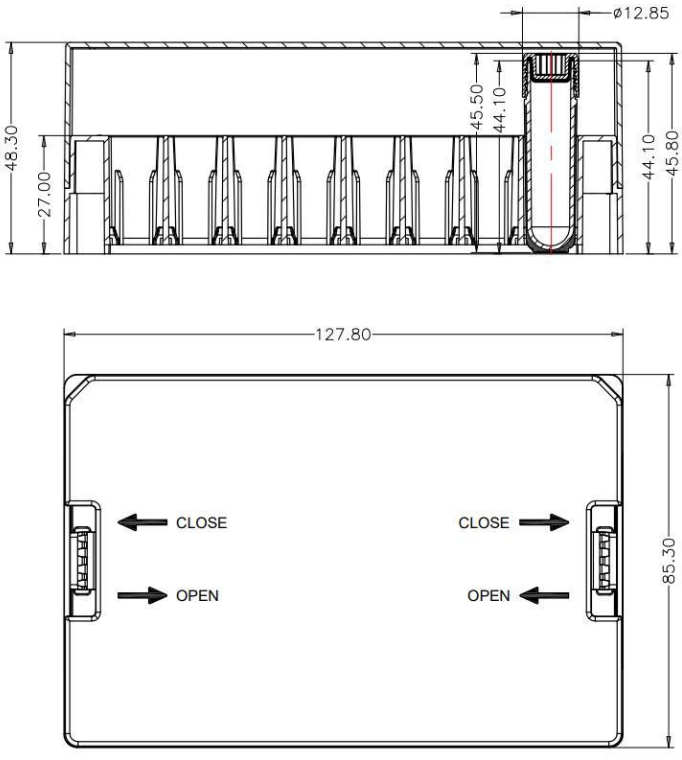


1.0mL external cap Three-in-One



2.0mL external cap Three-in-One

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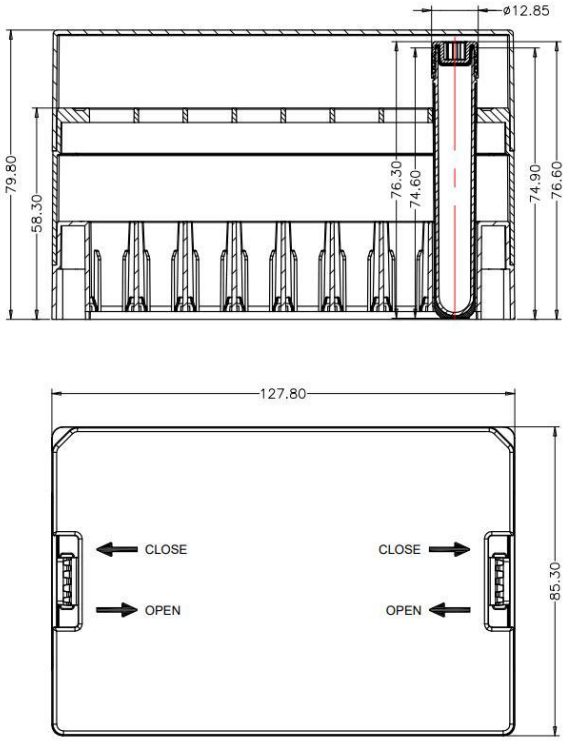
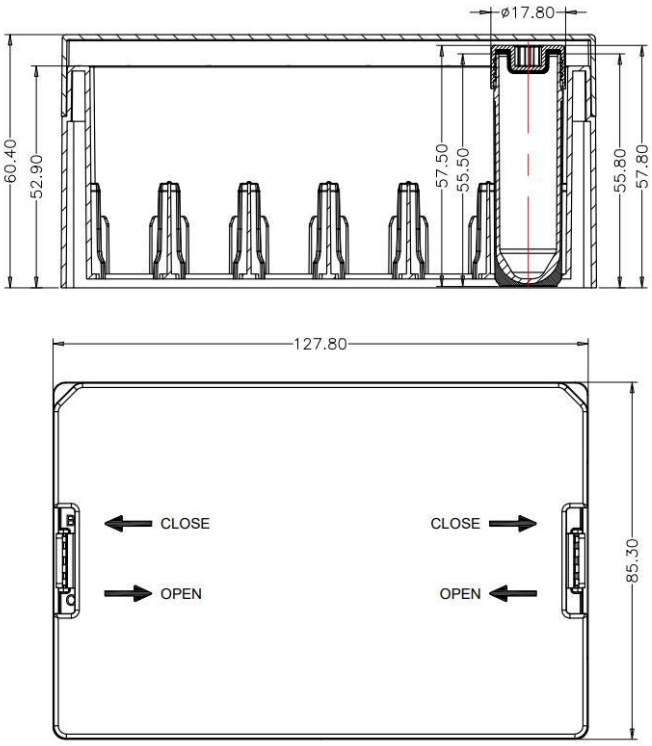
NEST Scientific Europe BV (Netherlands)
NEST Scientific (MENA) FZE (Sharjah, United Arab Emirates)



4.0mL external cap Three-in-One



6.0mL external cap Three-in-One

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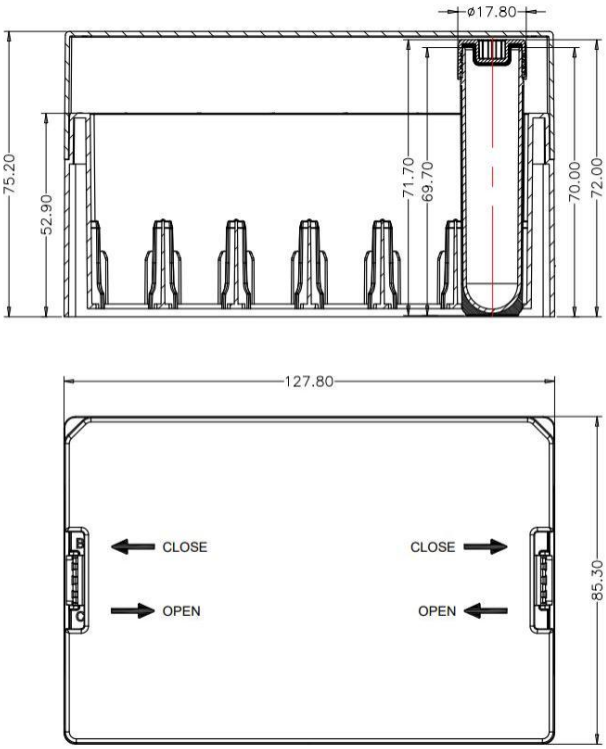

8.0mL external cap Three-in-One

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Attachment -9 COA sample

Wuxi NEST Biotechnology Co., Ltd

Certificate of Analysis

Product Name	2.0 mL Cryogenic Vial (External Thread, Sterile)	Product No.	607401	Lot No.	022425CT01
DOM	2025-02-24	Expiration Date		2030-01	

No.	Item	Inspection items/basis	Result
1	Appearance	① The tube body should be silk screen printed with scale, LOGO and writing area, the screen integrity is good, the color is white, there is no leakage, missing print, scratch, printing, layering, tilt, distortion, etc., the font and line thickness are normal, after 3M tape test, the screen printing is complete; Long rubber mouth: the bottom long rubber mouth does not exceed 0.20mm, drawing is not allowed.	Pass
2	Size	Comforming to the blueprint	Pass
3	Tightness test	After fitting the tube body and tube cover, negative pressure test, no water, no bubbling	Pass
4	Freezing test	Freezing test product no freezing crack, no leakage	Pass
5	High temperature sterilization	Take the product and put it into the high-pressure steam sterilizer for high temperature sterilization; Take out and observe that the product has no obvious deformation	Pass
6	Packaging	Correct packaging materials and quantity; intact packaging	Pass
7	Sterilization	Red colored irredriation tag with Certificate of Irradiation	Pass
8	*Sterility testing	No microorganisms can be detected	Pass
9	*Endotoxin Detection	≤0.05EU/ml	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'.
Items marked with "*" are periodic testing items for representative products.

Add: No.530, Xida Road, Meicun Industrial Park, Xinwu District, Wuxi	Tested by	Jiang Meiqi	Approved by	He Yun
Tel: (+86) 0510-68006788				
Fax: (+86) 0510-68006788	Date	2025-02-27	Date	2025-02-27
https://www.cell-nest.com				

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