See what it feels like when innovation is tailored to your needs

NEST

Reusable pen injector &Disposable pen injector

www.cell-nest.com

Contents

Company Introduction

Founded in 2009, Wuxi Nest Biotechnology Co., Ltd. (here in after referred to as “Nest”) is dedicated to research, development, and manufacturing of high-quality life sciences products.

Based on years of continuous investment in R&D and improvement of business chain, NEST's service scope covers the whole line of independent control from product design, process design, mold design and manufacturing, injection molding, surface treatment, irradiation sterilization, etc., and has the integration service capability of automation and flexibilization characteristics, which has formed the technological characteristics of independent innovation and rapid realization of products within the industry (including the business of cassette bottles).

The company now has 6800m^2 of 100,000 class clean room, 2700 disposable of 10,000 class clean room, reaching the international advanced level; at present, it has obtained ISO 9001, ISO 13485, ISO 11137, FDA, CE certification and medical device production license, and standardized production with reference to the GMP quality management standards, and it has passed the third-party's regular monitoring, which can ensure that the product manufacturing process and packaging process meet the standardized requirements.

The company’ s numerous products are exported to over 70 countries worldwide, including the United States, Germany, France, Japan, South Korea, India, and more. Our end customers include top domestic and international universities, as well as numerous life science research institutions. Our services extend to renowned international and domestic large enterprises and organizations, such as WHO, Thomas Scientific, Eurofins County Pathology Ltd, Kingfisher Biotech, WuXi AppTec, and more.

Nest also provides related services for automated assembly, liquid filling, and other related equipment.

NEST products are mainly: disposable laboratory consumables, pharmaceutical packages and medical devices.

Company Introduction

Development History

Dreams took shape

2009

The brand “NEST” was established and the supplies for cell cu

We offered:
Cell Culture Plates: 6/24/ 96 well
Cell Culture Flask: T25/T75
Cell Culture Dish: 35mm/60mm/90mm

2014

The newly constructed workshop, covering an area of 27,000 m^2,was officially inaugurated.
Introduced the Reusable Pen Injector
Incorporated RhodotronTT200 E-beam irradiation equipment from Belgium Sterilization Center obtained ISO11137 certification.

2010-2014
Carefully preparing for Cell Culture and Liquid Handling collection.We offered:
- Cell Culture Plate: 48/384-well Plate, 96-well U-shape/ V-shape Bottom Plate
- Pipette Tips with comprehensive specifications ranging from 10 to 1000uL
- Cryogenic vials, both internal and external threaded, with comprehensive specifications ranging from 0.5-4.8mL

Eagerly pioneering

2017

Enhanced the product portfolio for industrial clients.

2015-2017 Continued to elevate the product portfolios We released collections of BioFactory, Erlenmeyer Flask, and Reusable Pen Injector.

2018

Pioneered the medical device field by developing.China's first nasal spray delivery device for vaccines, and initiated the application for Class II Medical device certification.

Proactive innovation

2021

Crafting the Plan for a Global NEST Added a 3300m^2 Warehouse and R&D Center in New Jersey, USA

2023

Elevated the entire portfolio Committed to building a comprehensive solution system of tools and services.

Including:
Biobank collection: Cryogenic Tubes, Biobank Sample Management Software, Vertical Freezer Rack, and related equipment.
Pharmaceutical Containers: Pre-filled Syringe, Pre-filled Intranasal Atomiza-tion Device, and Disposable Pen
Injector.
Reagent: GelNESTTM Matrix, Fetal Bovine Serum (FBS), and regular medium for Cell Culture, etc.

Embracing A Brighter Future

2024

Certified through the Medical Device Single Audit Program (MDSAP)

Disposable Pen Injector
CDE: B20230000891
510(k) Number: K240961
DMF Number: 40744
Completed FTO reviews in China and the U.S., no patent risks identified.

Reusable Pen Injector
510(k) Number: K240774
Health Canada Medical Device Licence (MDL) Number: 112619
Completed FTO reviews in China and the U.S., no patent risks identified.
Successfully obtained Class II Medical Device Certificate.

Pen Injector Product Line + Supporting Products Overview

In the pen injector product area, NEST has introduced customizable pen injectors as well as the more convenient and safer pen injector assembly (in the future, NEST will introduce a full range of cartridge bottles). These products are widely used for the administration of drugs such as insulin, follicular hormone, growth hormone, antibiotics, etc., making it easy and safe for patients to inject their medications.

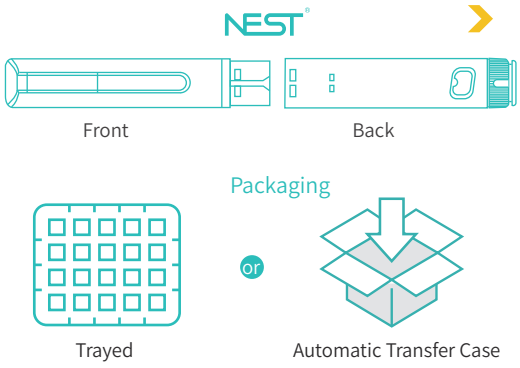
Product Name	Max. Single Dose	For Cartridge	Min. Single Dose	Usual Dose	Usual Scale Units	Applicative Drug
Disposable Pen Injector	36U	3mL	0.0208mL	0-12.5-25-…-450	IU	Follicle stimulating hormone,FSH
	37U	3mL	0.01mL	0-0.25-0.5	mg	Semaglutide, 1.34mg/mL , 0.5mg
	50U	3mL	0.01mL	0-0.6-1.2-1.8-2.4-3.0	mg	Liraglutide
	60U	3mL	0.01mL	0-1-2-...-60 even number	IU	Insulin Aspart series; Insulin glargine series
	74U	3mL	0.01mL	0-0.25-0.5-1.0 ;Customized	mg	Semaglutide(0.68mg/mL、1.34mg/mL、2.68mg/ml)
	75U	3mL	0.01mL	0-1mg; 0-1.7mg; 0-2.4	mg	Semaglutide
	80U	3mL	0.01mL	0-1-2-...-80 even number	IU	Insulin degludec/insulin aspart,IDegAsp
SP style Disposable Pen Injector	37U	3mL	0.01mL	0-0.25-0.5	mg	Semaglutide, 1.34mg/mL , 0.5mg
	50U	3mL	0.01mL	0-0.6-1.2-1.8-2.4-3.0	mg	Liraglutide
	60U	3mL	0.01mL	0-1-2-...-60 even number	IU	Insulin Aspart series; Insulin glargine series
	72U	3mL	0.01mL	0-450 IU	IU	Follicle stimulating hormone,FSH
	74U	3mL	0.01mL	0-0.25-0.5-1.0 ;Customized	mg	Semaglutide(0.68mg/mL、1.34mg/mL、2.68mg/ml)
	75U	3mL	0.01mL	0-1mg; 0-1.7mg; 0-2.4	mg	Semaglutide
	80U	3mL	0.01mL	0-1-2-...-80 even number	IU	Insulin degludec/insulin aspart,IDegAsp
Disposable fixed dose Pen Injector	8U	1.53mL	0.08mL	0- inject	IU	Parathyroid Hormone ; Drug for Osteoporosis
	8U	3mL	0.08mL	0- inject	IU	Drug for Osteoporosis:Teriparatide
Reusable Pen Injector	60U	3mL	0.01mL	0-1-2-...-60 even number	IU	Insulin Aspart series
	60U	3mL	0.0075mL	0-1-2-...-80 even number	IU	Human Growth Hormone
	75U	3mL	0.01mL	0-1mg; 0-1.7mg; 0-2.4mg	mg	Semaglutide
	80U	3mL	0.01mL	0-1-2-...-80 even number	IU	Insulin degludec/insulin aspart,IDegAsp ; Insulin glargine; Insulin glulisine

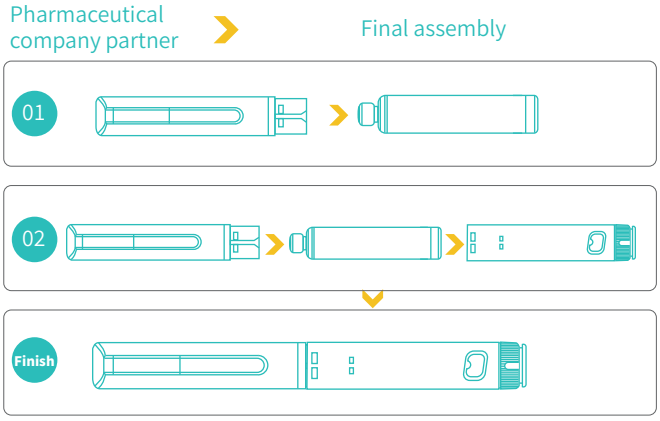
Product Introduction

CDE :B20230000891 510(k) NO. K240961

Disposable Pen Injector Assembly

Satisfy customer's needs



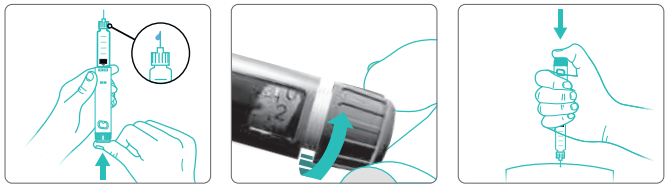


Product Feature

- Highly customizable: appearance, color, dosage, scale lines customizable.
- Currently available in 36/ 37 /50 /60 /74 /75 /80 units, which can be customized for different indications.
- Pressing force: 36/37 units <5N, 74/80 units <8N.
- Accurate dosage, professional R&D team and data validation support.
- Completed the FTO review in China and the United States, no patent risk.
- Applicable to liraglutide, simethicone, follicle stimulating hormone (FSH) drugs, insulin degludec and other drugs.
- Successfully applied for CDE number; CE MDR, FDA (510k) has been submitted for review.

Simple operation

It is easy for beginners to use, eliminating the need for professional guidance.



1、Preparation 2、Dose regulation 3、Injection

Trayed

Automatic Transfer Case

Disposable Prefilled Pen Injector

The NEST Automatic Pen Injector is a disposable auto-injection device designed for all patient groups. It provides an alternative to traditional syringe injections, reducing fear during medication administration and enhancing convenience and compliance. This product is compatible with 1 mL pre-filled glass or polymer syringes.

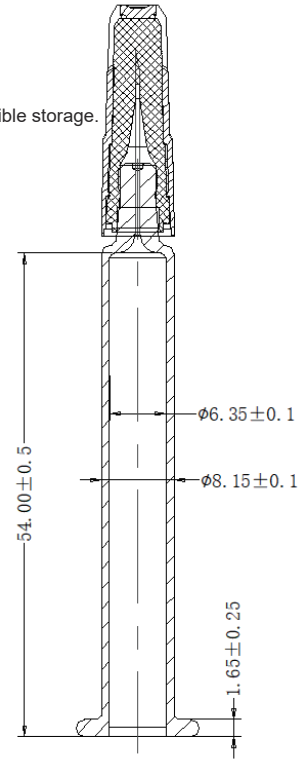
Product Feature

Compatibility with PFS Specifications: Suitable for 1mL or 2.25mL, filling volume: 0.2-2.25mL, adaptable to different drug dosages.

- Injection Method: Three-step operation for higher safety, preventing accidental triggering.
- Safety Design: Hidden needle design, automatic needle locking after injection to avoid needle-stick injuries.
- Injection Time: Less than 10 seconds (depending on filling volume, viscosity, and needle diameter).
- Needle Diameter: 29G or larger, needle insertion length: 6±2mm.
- Post-Injection Feedback: Auditory and visual feedback, transparent large window to remind users of the injection status.
- Compliance Standards: Meets ISO 11608-1/ISO 11608-5 testing requirements.
- Appearance Design: Triangular anti-roll cap design, supports horizontal or vertical placement for more convenient and flexible storage.
- Customization Flexibility: Appearance, color, and other features can be customized.

Product Specifications

Main Parameters	Description
Internal Container	1 mL slim-type PFS
Filling Volume	Determined by the client's medication weight
Injection Dose	Fixed dose
Needle Diameter	29 G TW or larger
Injection Time	≤ 10 seconds
Needle Penetration Depth	6 ± 2 mm
Injection Feedback	Visual and auditory feedback
Safety Lock Force	≥ 60 N
Needle Safety Distance	≥ 4.5 mm



1mL slim-type

Product Introduction

510(k) NO. K240774 MDL Number: 112619

Resuable Pen Injector

Product feature

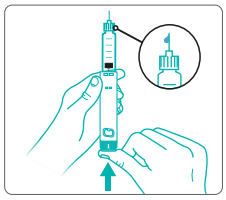
Scan the QR code
Watch use video

Small Window

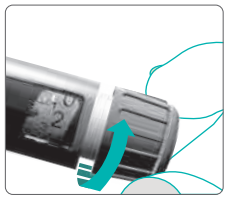
Large Window

Simple operation

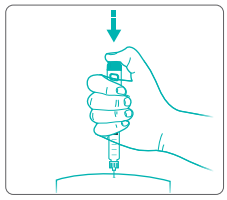
It is easy for beginners to use, eliminating the need for professional guidance.



1、Preparation



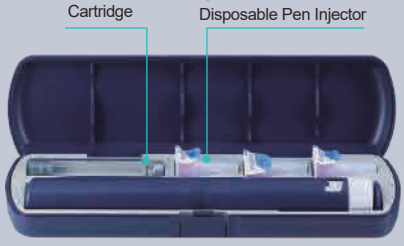
2、Dose regulation



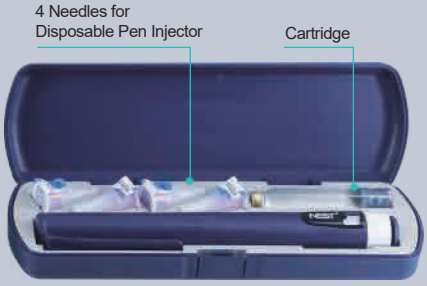
3、Injection

- Highly customizable: appearance, color, dosage, scale customizable.
- Current smallest is 0.75 units (0.0075mL) and the injection range covers 60 / 74 / 80 units; can develop according to different indications.
- Pressing force: 80 units <15N, 60 units <8N, accurate dosage, professional R&D team and data validation information support.
- Successfully obtained Class II medical device license, MDL, FDA (510k) .
- Used for long-term injection of insulin and other drugs.

Product packaging



Deluxe Version (3 needles)



Deluxe Plus Version (4 needles)

Reusable Pen Injector Customization Solution

Product Name	Max. Single Dose	For Cartridge	Min. Single Dose	Usual Dose	Usual Scale Units	Applicative Drug
Reusable Pen Injector	60U	3mL	0.01mL	0-1-2-…-60 even number	IU	Insulin Aspart series
	60U	3mL	0.0075mL	0-2-…-60 even number	IU	Human Growth Hormone
	75U	3mL	0.01mL	0-1mg; 0-1.7mg; 0-2.4mg	mg	Semaglutide
	80U	3mL	0.01mL	0-2-…-80	IU	Insulin degludec/insulin aspart,IDegAsp ; Insulin glargine; Insulin glulisine

Disposable Pen Injector Customization Solution

Product	Pen Injector Assembly			
Clien			Connact	
Intended Application			Email	
Appearance	Color	☐Regular: ☐Pink (36U) ☐Purple (37U) ☐Yellow (50U)		
		☐NEST Green (60U) ☐Orange (74U) ☐Green (75U) ☐Blue (80U)		
		☐Other: Pantone Color Code		
	LOGO	☐Without LOGO ☐Customizable Pattern	Cap	☐Long ☐Short
Dose	☐Regular: ☐36 U ☐37 U ☐50 U ☐60 U ☐74 U ☐75 U ☐80 U ☐Customizable: Min: Max:			
Graduation	☐Unit: ☐mg ☐iu ☐mL ☐Customizable:			
For Rubber Stopper	☐Long ☐Short			
For Cartridge	☐3.0 mL ☐1.5 mL			
Packaging	☐Trayed: Pen body: 60/tray, 16 tray/case, 960/case. Other Components: 240/pack, 960/case ☐Automatic Transfer Case: pen body: 240/tray, other Components: 240 /pack, 960/case ☐Other			
User Manual	☐Customizable			
Others				

Reusable Pen Injector Customization Solution

Product	Reusable Pen Injector 		
Client		Connact	
Intended Application		Email	
Appearance	Body Color	☐Regular: Blue ☐Other:	
	Dosage Adjustment Knob Color	☐Regular: White ☐Other:	
	Window	☐Small Dosage Display Window ☐Large Dosage Display Window	
	LOGO	☐Without LOGO ☐Customizable Pattern	
Dose & Graduation	Min. Single Dose	☐0.01mL ☐0.0075mL ☐Other:	
	Min. Single Dose	☐60 U ☐75 U ☐80 U ☐Other:	
	Graduation	☐mg ☐mL	
Packaging	☐Deluxe: ☐Plus (4 Needles+ 1 Cartridge) ☐Regular(3 Needles+ 1 Cartridge)		
User Manual	☐Customizable	Others	

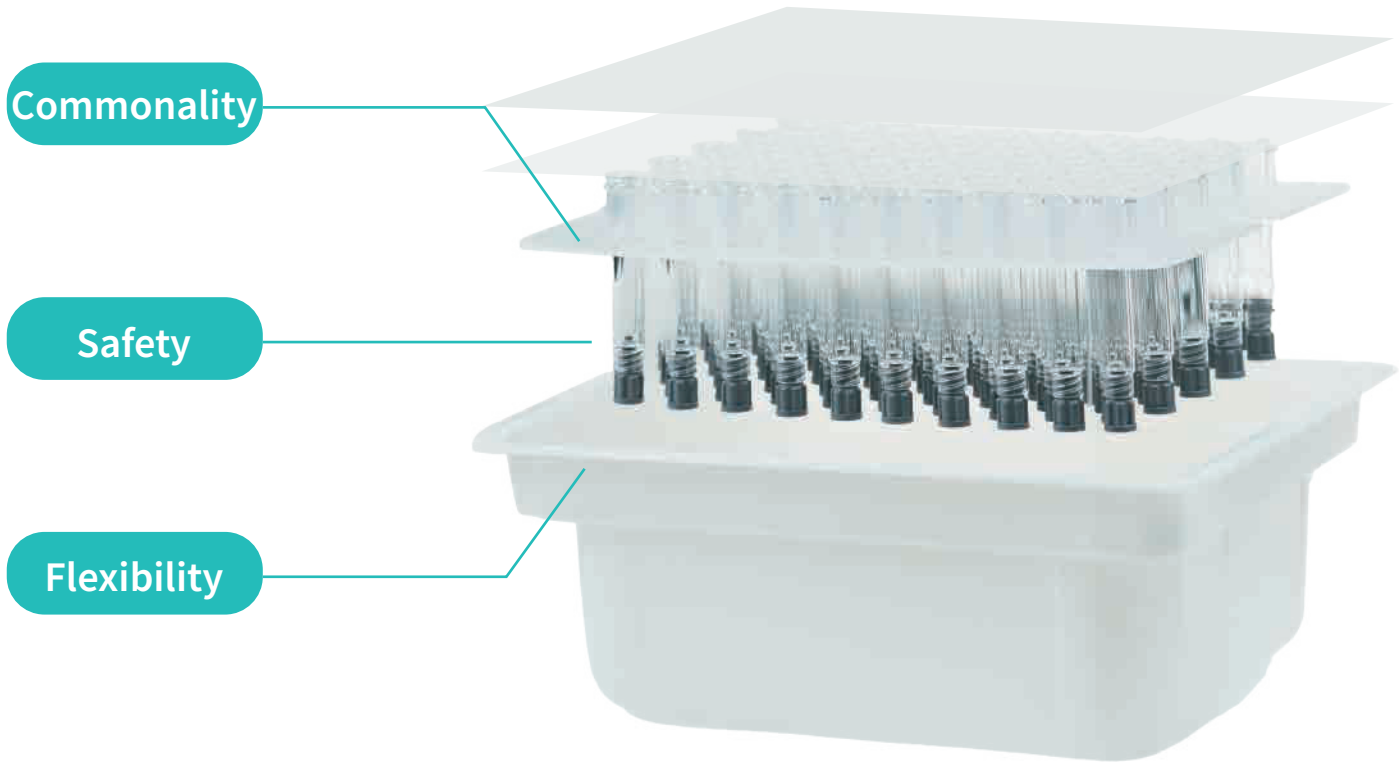
Product Introduction

Series of No-washing and No-sterilization

Utilizing an integrated washing and drying production line, the process is conducted under cleanroom conditions equivalent to those of pharmaceutical enterprises. This makes it suitable for direct filling and use by pharmaceutical companies, research institutions, and pilot-scale production facilities.

Advantages and Features

- **Simplified Filling Process:** Accelerates the drug launch process.
- **Sterilization Methods:** Utilizes moist heat/ethylene oxide sterilization.
- **Aseptic Delivery:** Reduces production costs for end-users.
- **Sterile, Ready-to-Use High-Quality Components:** Eliminates additional processing steps while fully meeting regulatory expectations, providing customers with a comprehensive container solution.
- **Enables Direct Filling for Small Pharmaceutical Companies, Research Institutions, and Pilot-Scale Facilities:** Meets the demand for reduced non-core operations and cost savings under the MAH (Marketing Authorization Holder) system.



Offer a variety of packaging options for injectable vials, cartridges and pre-filled syringes, including nest packaging and tray packaging

Pre-washing & pre-sterilization cartridge

Cartridges are the next-generation packaging solution for injectable drugs, widely used for insulin, GLP-1, hormones, and other medications.
This product is a new type of pharmaceutical packaging material. Liquid medication is directly stored in the cartridge, which serves as a standard packaging container for storing the drug. When in use, the cartridge is loaded into the Pen Injector along with an injection needle. By pushing the rubber stopper in the cartridge forward, the liquid medication is administered into the body through a disposable needle.

Empowering Pharmaceutical Companies to Seamlessly Achieve Leapfrog Production

- **Enhance Production Efficiency:** Pre-washed and sterilized, directly usable nest loading is suitable for rapid filling.
- **Reduce Investment Costs:** Save on facility and equipment investments for cleaning and sterilization, as well as operational and labor costs in the workshop.
- **Accelerate Product Launch:** Speed up the entire process of bringing new products to market, with particularly significant benefits during the R&D phase.

Production Process

- **Materials:** Made from imported borosilicate glass with excellent chemical stability, ensuring the stability of the medication.
- **Cleaning:** Containers are cleaned using injection-grade water.
- **Siliconization and Depyrogenation:** A unique siliconization process uniformly treats the inner surface of the cartridge, followed by advanced baking technology to cure the silicone oil coating, which also achieves depyrogenation.
- **Pre-Capping:** Fully automatic capping system ensures a perfect fit for the cartridge.
- **Nest Box Assembly:** The appropriate spacing between the wells in the nest tray prevents glass-to-glass contact, reducing the risk of container breakage and enhancing product safety.
- **Sealing and Sterile Packaging:** Tyvek® sealing ensures maximum sterility and cleanliness.
- **Sterilization:**Steam sterilization is employed, providing a more environmentally friendly and safer option than ethylene oxide sterilization.

Description	/Pack /Case	Cat.No.
3.0 mL Cartridge Assembly	100 units per box, 15 boxes per carton.	217231

Product Introduction

A safer sterilization method

- Steam sterilization is more environmentally friendly compared to EO and offers higher safety, with a Sterility Assurance Level (SAL) of 10^{-6}

Fully Automated Inspection System

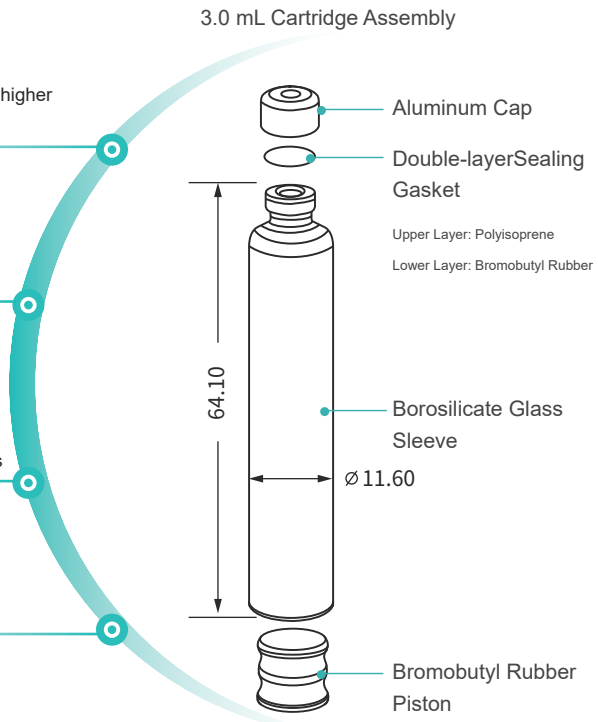
- 100% inline optical inspection ensures excellent appearance quality

High-precision and advanced equipment

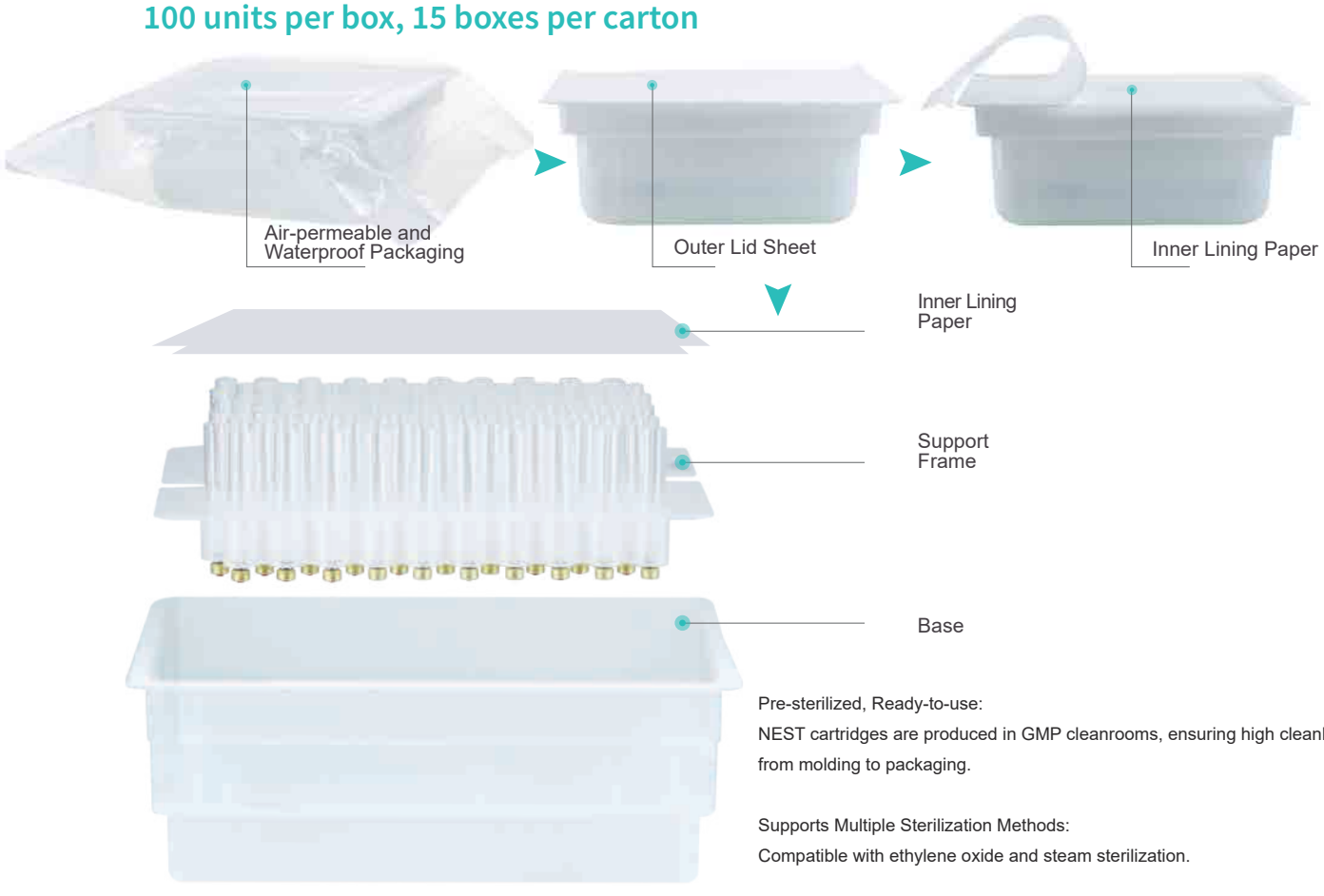
- utilizes advanced cleaning and automated assembly lines, maintaining a production environment with partial areas meeting Class 100 standards, resulting in low particulate contamination and full compliance with regulatory requirements

Packaging safety

- Cartridge Assembly packed in nest trays, preventing glass-to-glass contact and reducing the risk of container breakage, thereby enhancing product safety



100 units per box, 15 boxes per carton



Pre-sterilized, Ready-to-use:
NEST cartridges are produced in GMP cleanrooms, ensuring high cleanliness from molding to packaging.

Supports Multiple Sterilization Methods:
Compatible with ethylene oxide and steam sterilization.

COP prefilled syringe

NEST COP Pre-filled Syringes are in high demand in the pharmaceutical market due to their small size, portability, accurate drug dosage provision, and low risk of contamination. They are widely used as a container of high-value products such as biologics, biochemical products, anti-thrombotic drugs, and beauty products Serving. as alternatives to borosilicate glass,cyclic olefin polymers (COP) offers a high degree of flexibility in design. Its high crack-resistance also reduces logistics and transportation costs. In terms of other physical and chemical properties, COP exhibits high transparency, rigidity, heat resistance, low refractive index, low protein adsorption, and is free from heavy metals and tungsten. Compatibility tests with pharmaceuticals indicate no delamination. And it can be manufactured with low or no silicone content, addressing the limitations of glass pre-filled syringes.

NEST COP Pre-filled Syringe is designed to meet your ever-changing needs. We offer comprehensive process services, which include design, production, and pre-sterilization, to provide you with the perfect solution.

Application

- Container for biological agents (such as GLP-1, hormones, monoclonal antibodies)
- Ophthalmic applications
- Emergency drugs
- Vaccines
- Medical aesthetic drugs
- Compatible with automatic injectors

Key Features

- Excellent drug stability, low protein adsorption, and barrier properties against water vapor and oxygen permeation.
- Eliminates the need for drug reconstitution before injection, reducing the risk of drug contamination.
- Accurate drug composition, avoiding changes in drug proportions during on-site drug preparation.
- Luer Connector, in line with the International Standard, is included to ensure secure connections and achieve excellent sealing performance. This reduces drug leakage and prevents the risk of needle rotation and popping during injection.
- COP offers a high degree of design flexibility and allows for greater customization.
- Compatible with various sterilization methods, such as ethylene oxide sterilization and steam sterilization.
- Complies with ISO 9001, ISO 15378, YBB, and USP Class VI standards.

Advantages of COP material compared to other materials.

Features	COP	Glass	PP
Gas permeability (O2, N2, CO2)	M	G	M
Water vapor permeability	G	G	M
Transparency after steam sterilization	G	G	P
Transparency after EP sterilization	G	G	P
Transparency after gamma ray sterilization	G	G	P
Drug pH change	G	P	G
Brittleness	G	P	G
Precision Molding/processing type	G	P	G
Waste characteristics/combustion characteristics	G	P	G
High purity	G	G	M

Remark：G-Good,M-Moderate,P-Poor

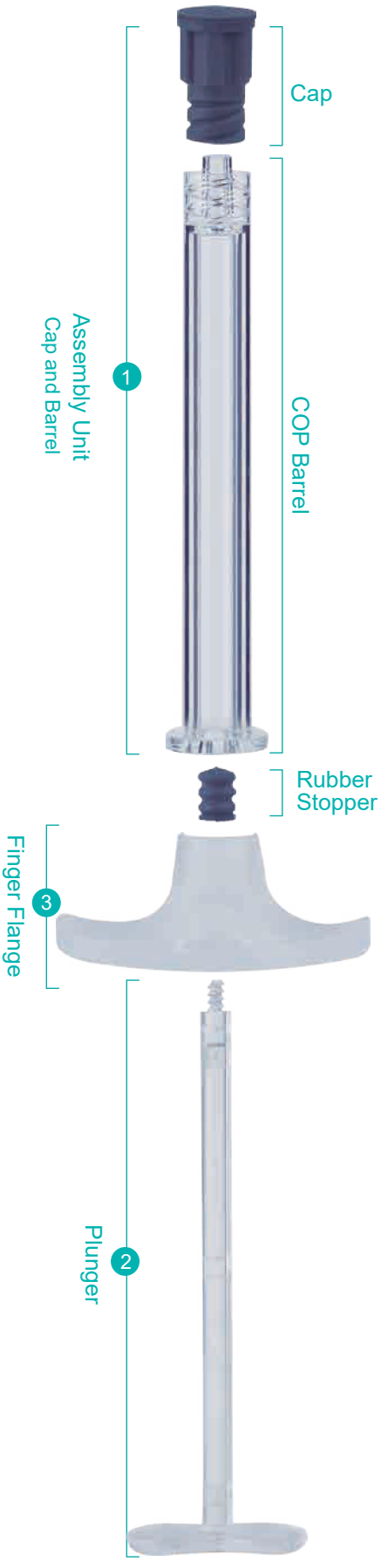
10x10 Nested Configuration

The specification for pre-sterilized wash-free and sterilization-free NEST Pre-filled Disposable Glass Intranasal Atomization Device is now available. They are produced in a cleanroom that adheres to GMP management standards, from injection molding to final packaging.

State-of-the-art automated production process is adopted to ensure minimal tolerance and stable quality of the barrel.

Suitable for various sterilization methods, including ethylene oxide and steam sterilization.

Product Introduction



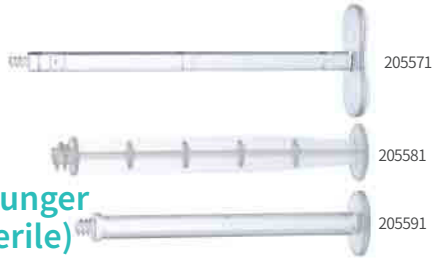
Rubber Stopper and Luer Cap

Made of butyl rubber bromide and compliant with European Pharmacopoeia, United States Pharmacopoeia, and Japanese Pharmacopoeia.

Product	Material	Rubber Stopper Formulation	Color
Rubber Stopper	Butyl Bromide	HS264	Black
Luer Cap	Butyl Bromide	HM174	Gray

Order Information for Assembly Unit

Specifications	Packaging		Cat.NO.	Matching Accessories
	/Pack	/Case		
1.0 mL	100	1500	205512	Plunger205591/Finger Flang205592
1.0mL Slender	100	1500	205502	Plunger205571/Finger Flang205572
2.25 mL	100	1500	205522	Plunger205581/Finger Flang205582



Order information for Plunger (Double-bagged, non-sterile)

Specifications	Packaging		Cat.NO.	Matching Accessories
	/Pack	/Case		
1.0 mL	5000	5000	205591	Assembly Unit 205512/ Finger Flang205592
1.0mL Slender	5000	5000	205571	Assembly Unit 205502/ Finger Flang205572
2.25 mL	5000	5000	205581	Assembly Unit 205522/ Finger Flang205582

Order information for Finger Flanger (Double-bagged, non-sterile)

Specifications	Packaging		Cat.NO.	Matching Accessories
	/Pack	/Case		
1.0 mL	10000	10000	205592	Assembly Unit 2205512/ Plunger 205591
1.0mL Slender	10000	10000	205572	Assembly Unit 2205502/ Plunger 205571
2.25 mL	10000	10000	205582	Assembly Unit 2205522/ Plunger 205581

Quality System

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

ISO9001、ISO13485

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.

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.

Medical Device Manufacturing License

NEST obtained medical device manufacturing license in 2021. We have a wide range of medical products including customizable pen injectors, pen injector assemblies, and disposable intranasal atomization devices. High-precision pen injectors are difficult medical devices that require high-precision processing equipment and technology and strict quality control. Therefore, obtaining a license to manufacture high-precision pen injectors requires a high level of technical strength and quality assurance. We apply the same technical strength and quality control requirements to our laboratory consumables.

YY/T 1768.1-2021; YY/T 1768.2-2021

NEST pen injectors are developed and tested based on the “Needle-based injection systems for medical use- requirements and test methods” YY/T 1768.1-2021 (ISO 11608-1:2014, NEQ) and YY/T 1768.2-2021 (ISO 11608-2:2012, NEQ) of the People's Republic of China pharmaceutical industry. We strictly adhere to these standards to ensure that our products meet the requirements and demonstrate reliability and effectiveness.

ISO9001

ISO13485

FDA

Cert 40744

Medical Device Registration Certificate of PRC

Quality Assurance

Product Performance Validation

Pen Injector Related Validation Reports

Disposable Pen Injector Dose Accuracy Verification Project

Product Performance Verification Tests	Periodic Monitoring Tests	Batch Release Tests
Injection button trigger force testing	Product performance lifecycle test	Appearance inspection
Final dose accuracy testing		Cartridge chamber labeling inspection
Free-fall dose accuracy testing		Injection dose labeling inspection
Cool/Standard/Warm ambient environment dose accuracy testing		Injection dose knob stability testing
Dry heat/Frozen atmospheric environment dose accuracy testing		
Vibration Test Dose Accuracy Testing		
Cool/Standard/Warm ambient environment injection resistance, leakage check, and needle compatibility testing		
Dry heat/Frozen atmospheric environment injection resistance, leakage check, and needle compatibility testing		
Vibration test injection resistance, leakage check, and needle compatibility testing		
Stability Validation Testing		

The test report in this chapter is for the 80-unit specification and is used to represent the report for all specifications of the pen injector assembly.
The tests in this chapter are performed in accordance with the national standard YY/T 1768.1 -2021 (ISO 11608- 1:2014, NEQ) and YY/T 1768.2-2021 (ISO 11608-2:2014, NEQ). For other test reports apart from the ones provided in this chapter, please contact us to obtain them.

Product Performance Verification Tests

Injection button trigger force test:

Under cool/standard/warm/dry heat/freezing atmospheric conditions, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, with injection resistance all being <30 N. The injection button activation force meets the standards.

Final Dose Accuracy Test:

Purified water is used as the testing medium, with needles and pen injectors selected according to standards. All other doses are expelled, and the final dose (Vmin: 0.01mL) is tested. The dose accuracy meets the standards.

Free-fall Dose Accuracy Test:

Purified water is used as the testing medium, with needles and pen injectors selected according to standards. The injectors are dropped freely from a height of 1000mm to the testing surface. After the free-fall test, injection tests are conducted for the minimum, intermediate, and maximum doses. The dose accuracy after free fall meets the standards.

Cool/Standard/Warm Ambient Environment Dose Accuracy Test:

After being placed in cool/standard/warm atmospheric conditions for 4 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, and injection tests are performed for the minimum, intermediate, and maximum doses. The dose accuracy meets the standards.

Dry Heat/Frozen Atmospheric Environment Dose Accuracy Test:

After being placed in dry heat/freezing atmospheric conditions for 96 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, and injection tests are performed for the minimum, intermediate, and maximum doses. The dose accuracy meets the standards.

Vibration Test Dose Accuracy Test:

The vibration test is conducted by alternating between frequency ranges of 3Hz~8Hz and 8Hz~300Hz, with 4 cycles in each direction. After the vibration test, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, and injection tests are performed for the minimum, intermediate, and maximum doses. The dose accuracy after the vibration test meets the standards.

Cool/Standard/Warm Ambient Environment injection resistance, leakage check, and needle compability testing:

After being placed in cool/standard/warm atmospheric conditions for 4 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards. The dose is adjusted to the maximum displayed dose, and tested using a pull-off force tester, with the maximum starting force and injection resistance both being <30 N. After the test, the dose is adjusted from the minimum dose to the maximum dose, then from the maximum dose back to zero. The needle leakage volume is <0.01mL. After the test, the needle seat assembly torque is tested, with the needle assembly torque value ranging from 0.060 N·m to 0.080 N·m. Following the test, alternating tests are performed at both the minimum and maximum doses to verify needle dose accuracy. After the test, the needle seat disassembly torque is tested, with the disassembly torque being <0.100 N·m. All five tests meet the standards.

Quality Assurance

Dry heat/Frozen atmospheric environment injection resistance, leakage check, and needle compatibility testing:

After being placed in dry heat/freezing atmospheric conditions for 96 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards. The five tests included in 'injection resistance, leakage check, and needle compatibility' are repeated, and the products meet the standards.

Vibration test injection resistance, leakage check, and needle compatibility testing:

The vibration test is conducted by alternating between frequency ranges of 3Hz~8Hz and 8Hz~300Hz, with 4 cycles in each direction. After the vibration test, purified water is used as the testing medium. Needles and pen injectors are selected according to standards. The five tests included in 'injection resistance, leakage check, and needle compatibility' are repeated, and the products meet the standards.

Stability Validation Testing:

According to the standards, the pen injector is placed in the aging chamber for accelerated aging, with 28 days (1-year shelf life), 85 days (3-year shelf life), and 141 days (5-year shelf life) of exposure in the aging chamber for each condition. Verification is conducted for each aging condition. The test items include appearance, cartridge dose labeling, injection dose labeling, injection dose knob stability, injection dose accuracy in cool/standard/warm atmospheric conditions, injection resistance tests in cool/standard/warm/dry heat/freezing atmospheric conditions, free-fall test, dry heat-freezing experiments, and leakage amount checks, for a total of nine tests. The test results meet the standards.

Periodic Monitoring

According to the standard YY/T 1768.1-2021 (ISO 11608- 1:2014, NEQ), periodic monitoring is required every year, excluding stability testing. It involves repeating the verification of product performance for all other test items.

Batch Testing

Appearance Inspection:

Based on the technical performance specifications of the pen injector, a visual inspection of the product's appearance is conducted. The product surface should be free of defects affecting appearance, such as flash, patterns, shrinkage, flow marks, scratches, etc. There should be no internal cracks, and the printed labels should be clear.

Cartridge Chamber Labeling Inspection:

Based on the technical performance specifications of the pen injector, a visual inspection of the product's appearance is conducted. The cartridge should be inspected for the presence of the cartridge vial dose (IU) labeling. The cartridge should be transparent, allowing the volume of the injected medication and the remaining medication to be visibly observed.

Injection Dose Labeling Inspection:

Based on the technical performance specifications of the pen injector, a visual inspection of the product's appearance is conducted. The dose setting scale lines and corresponding values should be clearly visible through the window. The scale lines should be evenly distributed, and the numbers on the injection dose scale lines should be clear.

Injection Dose Knob Stability Test:

Based on the technical performance specifications of the pen injector, the injection dose knob is tested. Each time the knob is rotated to an integer scale, a "click" sound should be heard. After setting the injection dose, it should be possible to reset the dose. The test results meet the standards.

Quality Assurance

Reusable Pen Injector Injection Resistance, Needle Compatibility, and Leakage Check Verification Project

Product Testing Summary

Product Performance Verification Tests	Periodic Monitoring Tests	Batch Release Tests
Injection button trigger force testing	Product performance lifecycle test	Appearance inspection
Final dose accuracy testing		Cartridge chamber labeling inspection
Free-fall dose accuracy testing		Injection dose labeling inspection
Cool/Standard/Warm ambient environment dose accuracy testing		Injection dose knob stability testing
Dry heat/Frozen atmospheric environment dose accuracy testing		
Humidity environment dose accuracy test		
Vibration Test Dose Accuracy Testing		
Cool/Standard/Warm ambient environment injection resistance, leakage check, and needle compatibility testing		
Dry heat/Frozen atmospheric environment injection resistance, leakage check, and needle compatibility testing		
Humidity environment injection resistance, leakage check, and needle compatibility test		
Vibration test injection resistance, leakage check, and needle compatibility testing		
Lifecycle testing		
Cycling test		
Stability Validation Testing		

The tests in this chapter are performed in accordance with the national standard YY/T 1768.1 -2021 (ISO 11608- 1:2014, NEQ) and YY/T 1768.2-2021 (ISO 11608-2:2014, NEQ). For other test reports apart from the ones provided in this chapter, please contact us to obtain them.

Product Performance Verification Tests

Injection button trigger force testing:

Under cool/standard/warm/dry heat/freezing atmospheric conditions, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, with injection resistance all being <30 N. The injection button activation force meets the standards.

Final Dose Accuracy Test:

Purified water is used as the testing medium, with needles and pen injectors selected according to standards. All other doses are expelled, and the final dose (Vmin: 0.01mL) is tested. The dose accuracy meets the standards.

Free-fall Dose Accuracy Test:

Purified water is used as the testing medium, with needles and pen injectors selected according to standards. The injectors are dropped freely from a height of 1000mm to the testing surface. After the free-fall test, injection tests are conducted for the minimum, intermediate, and maximum doses. The dose accuracy after free fall meets the standards.

Cool/Standard/Warm Ambient Environment Dose Accuracy Test:

After being placed in cool/standard/warm atmospheric conditions for 4 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, and injection tests are performed for the minimum, intermediate, and maximum doses. The dose accuracy meets the standards.

Dry Heat/Frozen Atmospheric Environment Dose Accuracy Test:

After being placed in dry heat/freezing atmospheric conditions for 96 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, and injection tests are performed for the minimum, intermediate, and maximum doses. The dose accuracy meets the standards.

Humidity Environment Dose Accuracy Test:

After placing in a humid environment for 96 hours, use purified water as the test medium, and select the needle and pen injector according to the standards. Conduct injection tests for the minimum, intermediate, and maximum doses. The dose accuracy meets the standard.

Vibration Test Dose Accuracy Test:

The vibration test is conducted by alternating between frequency ranges of 3Hz~8Hz and 8Hz~300Hz, with 4 cycles in each direction. After the vibration test, purified water is used as the testing medium. Needles and pen injectors are selected according to standards, and injection tests are performed for the minimum, intermediate, and maximum doses. The dose accuracy after the vibration test meets the standards.

Quality Assurance

Cool/Standard/Warm Ambient Environment injection resistance, leakage check, and needle compability testing:

After being placed in cool/standard/warm atmospheric conditions for 4 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards. The dose is adjusted to the maximum displayed dose, and tested using a pull-off force tester, with the maximum starting force and injection resistance both being <30 N. After the test, the dose is adjusted from the minimum dose to the maximum dose, then from the maximum dose back to zero. The needle leakage volume is <0.01mL. After the test, the needle seat assembly torque is tested, with the needle assembly torque value ranging from 0.060 N·m to 0.080 N·m. Following the test, alternating tests are performed at both the minimum and maximum doses to verify needle dose accuracy. After the test, the needle seat disassembly torque is tested, with the disassembly torque being <0.100 N·m. All five tests meet the standards.

Dry heat/Frozen atmospheric environment injection resistance, leakage check, and needle compatibility testing:

After being placed in dry heat/freezing atmospheric conditions for 96 hours, purified water is used as the testing medium. Needles and pen injectors are selected according to standards. The five tests included in 'injection resistance, leakage check, and needle compatibility' are repeated, and the products meet the standards.

Humidity environment injection resistance, leakage check, and needle compatibility test:

After placing in a humid environment for 96 hours, use purified water as the test medium. Select the needle and pen injector according to the standards, and repeat the five tests included in 'Injection resistance, leakage check, and needle compatibility.' The product meets the standard.

Vibration test injection resistance, leakage check, and needle compatibility testing:

The vibration test is conducted by alternating between frequency ranges of 3Hz~8Hz and 8Hz~300Hz, with 4 cycles in each direction. After the vibration test, purified water is used as the testing medium. Needles and pen injectors are selected according to standards. The five tests included in 'injection resistance, leakage check, and needle compatibility' are repeated, and the products meet the standards.

Lifecycle Testing:

Select 3 products that have passed the dose accuracy and resistance tests in cool, standard, and warm atmospheric environments (using new cartridges). Simulate the operation of the pen injector's components (removing the connection cap, needle, and injected drug, etc.) for 4,500 cycles (1.5 times the expected lifespan). After this operation, repeat the dose accuracy and resistance tests under standard atmospheric conditions. The products meet the standard.

Cycling Test:

Select pen injectors with cartridges and perform alternating tests as per the standard (see GB/T 2423.4—2008, Figure 2a), with low temperature, high temperature, and 6 cycles of operation. After this operation, repeat the dose accuracy and resistance tests under standard atmospheric conditions. The products meet the standard.

Stability Validation Testing:

According to the standards, the pen injector is placed in the aging chamber for accelerated aging, with 28 days (1-year shelf life), 85 days (3-year shelf life), and 141 days (5-year shelf life) of exposure in the aging chamber for each condition. Verification is conducted for each aging condition. The test items include appearance, cartridge dose labeling, injection dose labeling, injection dose knob stability, injection dose accuracy in cool/standard/warm atmospheric conditions, injection resistance tests in cool/standard/warm/dry heat/freezing atmospheric conditions, free-fall test, dry heat-freezing experiments, and leakage amount checks, for a total of nine tests. The test results meet the standards.

Periodic Monitoring

According to the standard YY/T 1768.1-2021 (ISO 11608- 1:2014, NEQ), periodic monitoring is required every year, excluding stability testing. It involves repeating the verification of product performance for all other test items.

Batch Testing

Appearance Inspection:

Based on the technical performance specifications of the pen injector, a visual inspection of the product's appearance is conducted. The product surface should be free of defects affecting appearance, such as flash, patterns, shrinkage, flow marks, scratches, etc. There should be no internal cracks, and the printed labels should be clear.

Cartridge Chamber Labeling Inspection:

Based on the technical performance specifications of the pen injector, a visual inspection of the product's appearance is conducted. The cartridge should be inspected for the presence of the cartridge vial dose (IU) labeling. The cartridge should be transparent, allowing the volume of the injected medication and the remaining medication to be visibly observed.

Injection Dose Labeling Inspection:

Based on the technical performance specifications of the pen injector, a visual inspection of the product's appearance is conducted. The dose setting scale lines and corresponding values should be clearly visible through the window. The scale lines should be evenly distributed, and the numbers on the injection dose scale lines should be clear.

Injection Dose Knob Stability Test:

Based on the technical performance specifications of the pen injector, the injection dose knob is tested. Each time the knob is rotated to an integer scale, a "click" sound should be heard. After setting the injection dose, it should be possible to reset the dose. The test results meet the standards.

Quality Assurance

Automated production equipment

Especially for large-scale production in the pharmaceutical and healthcare industries, automation that is precisely coordinated with products, projects, and processes has a decisive impact on both production quality and economic efficiency.

Automation is an integral part of our product and process development. Our expertise is embedded in product development as early as the concept and design stages. Automation solutions are not formulated only when mass production begins; instead, they are developed as early as the prototype and pre-production stages, saving time in production. If external solutions are required for mass production, our knowledge and information can also be shared with the external automation system manufacturer.

Automated production lines play a crucial role in ensuring production quality and economic efficiency. The automated assembly equipment used in NEST pen injectors is a key component of our product and process development, significantly contributing to both product quality and production capacity.

Reusable pen injector assembly equipment

Main processes:

- Drum feeding
- Height testing
- Press fitting and testing
- Gear assembly
- Bracket assembly
- Torque testing (low torque value) (<4N.CM)
- Pen cap assembly
- Good/bad product ejection
- Integrated technology with flexible modular and standardized high-speed platform

Main parameters:

- The equipment adopts integrated technology with a flexible modular and standardized platform
- Efficiency: 7 units/min
- Linear system – smaller footprint
- Progressive investment: Initial investment for a basic machine with a capacity of 7 ppm; next investment upgrade to FMS 2M or 40 ppm
- Simple design, higher machine efficiency
- Equipment dimensions: 6000mm (L) x 4500mm (W)

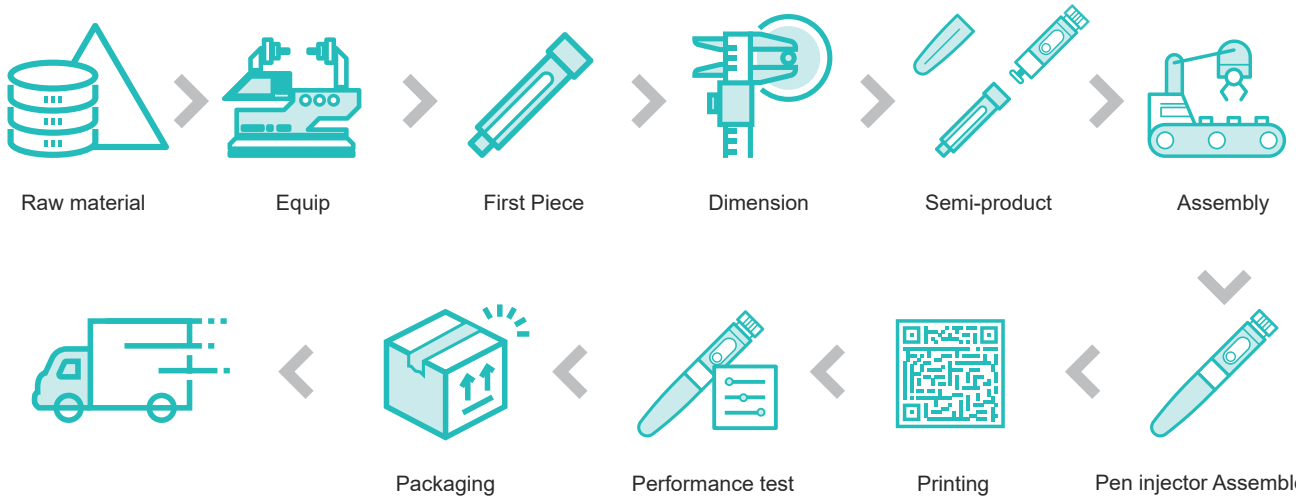
Disposable pen injector assembly equipment

- The equipment adopts a flexible standard modular design: 60% standard platform, 40% customized
- Fully automated production with inline torque testing
- Efficiency: 100 units/min
- Equipment dimensions: 8000mm (L) × 5500mm (W)
- Linear system: smaller footprint with higher flexibility
- Carriers: modular design allows easy replacement for different products, ensuring convenient operation
- Progressive investment: initial efficiency is 100 ppm, with future upgrade potential to 160 ppm
- Automatic feeding: circular components use a low-noise, wear-free step feeder; some vibrating bowls can also enable automatic material clearing
- The equipment ensures all push rods maintain a uniform height position

Production Management

Production Process Control / Key Milestone Quality Inspection

Nest's Quality Management ensures quality from the very beginning—starting at the mold development and production stages—by utilizing various advanced equipment to guarantee product excellence. This approach allows us to embed "high quality" throughout both our products and production processes. Regardless of the stage in the manufacturing process, our quality assurance team is actively involved and works closely with other relevant departments to maintain the highest standards.



Periodic Testing

Product Quality and Sterility Control

During the product validation process, Nest conducts testing on all performance items of the product according to internal product technical requirements to ensure that the product meets design specifications. Nest's products undergo design verification, process window verification, performance verification, small batch trial production, and three-batch mass production tracking during the development phase to ensure that product production is stable and reliably meets design requirements.

Once the product has been validated and mass production is achieved, some of the earlier validated product performance testing items will be converted into periodic monitoring and batch testing items for quality control. Periodic monitoring is conducted regularly according to different products and testing items. Batch testing is performed before each batch of products is processed and released to ensure that product quality issues can be identified, intercepted, and corrected in a timely manner during the production process.

Product performance verification

Product performance verification refers to a series of tests and validations conducted to check whether the product meets the predefined performance parameters and whether it satisfies the user's usage requirements. The results of the verification can be used to determine whether the product can proceed to the next stage of development or production. These verifications include, but are not limited to:

- Finished product application performance verification
- Finished product shelf life verification
- Finished product transportation verification

Batch Testing

Process inspection and batch release inspection are important methods in product quality management. They allow for quality control of semi-finished products and finished products before release, ensuring the stability and consistency of product quality. The advantage of batch testing is that it can quickly identify issues 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:

- Free fall testing
- Trigger force testing
- Injection dose dial stability testing
- Appearance and packaging inspection

Periodic Testing

Periodic monitoring of products refers to the regular testing and evaluation of finished products to ensure that they continue to meet quality and performance requirements during use. This testing helps to identify certain issues that may have a moderate risk level in the production process or quality inspection process, and allows for timely corrective actions or replacements. Periodic monitoring typically varies based on product type and usage, and includes, but is not limited to:

- Dose accuracy testing
- Resistance testing
- Vibration resistance testing
- Stability testing

Quality Assurance

Personnel and Quality Control Equipment

Quality Team, R&D Team

1.Professional Team Structure

- The 76-person professional team is proficient in core quality tools such as APQP and FMEA, and has passed multiple system certifications
- A dedicated team is established to handle raw material analysis, product testing, and other processes

2.Full-Process Quality Control System

- Raw Material Testing: Physical and chemical analysis + component damage diagnostics
- Product Verification: Dual functionality testing for components and the complete unit
- Method Certification: Standardized verification of measuring equipment and testing processes

3.Standardization Certification System

- International Standards: ISO 9001/IATF 16949/ISO 13485 system certifications
- Professional Qualifications: All team members have undergone internal auditor training and are certified
- Testing Standards: Customized testing plans based on customer standards

4.Quality Closed-Loop Management

Test Data → Functional Testing Group Execution → Quality Engineer Evaluation → Final Review by Project Manager (Quality Engineering Department)
(Based on the characteristics of the quality management system, the core elements are integrated, with a focus on professional division of labor and standardized processes.)

Certification and Verification of Production Equipment, Processes, and Measuring Equipment

Experience with three-coordinate measuring system (Germany ZEISS, CONTURA 7/10/6RDS)

In practice, we extensively use three-coordinate measuring system for dimensional measurement of mold processed parts, fixtures, complex products, and experimental samples. The data is output and analyzed through a computer, ensuring high reliability. The coordinate measuring machine uses high-precision optical positioning technology and advanced data processing techniques, ensuring the reliability and stability of the measurement data.

Dimension Scanner (Japan Keyence, IM-8030)

Used for dimensional recognition and remodelling, the dimension scanner allows us to measure and analyze the surface dimensions of materials simply through computer processing. It enables fast, repeatable surface dimension measurements (e.g., measuring the same dimension across multiple holes) using the computer system.

Packaging Tear and Peel Strength Tester (YBB-03)

The YBB-03 Pharmaceutical Packaging Tear Strength Tester is mainly used for accurately measuring the pressing force and holding force of pen injectors, as well as conducting tensile, peel, opening force, puncture force, and breakage tests on pharmaceutical packaging materials such as rubber stoppers, combination caps, composite films, aluminum foil, and PVC sheets. It is also used for testing pre-filled syringes, ampoule breakage force, and sliding performance. It is suitable for research institutions, pharmaceutical companies, inspection and quarantine agencies, and other organizations.

Visual and Tactile Measurement Technology and Industrial Computed Tomography

The measurement laboratory equipped with modern measurement instruments ensures that precision mold inserts, injection molded parts, or assembly units can be measured with extreme accuracy. Complete component measurement data is recorded in the initial sample test report after measurement. These devices include various multi-sensor coordinate measuring machines for visual and tactile component measurement, universal measurement microscopes, and industrial computed tomography scanners for non-destructive measurement and testing of individual parts or entire assembly units.

Full Industry Chain Structure

R&D and Mould Manufacturing

Nest has the capability to independently design and develop molds. Based on your specific requirements, we can customize the development and optimize the injection molding layout for pen injectors. By embedding production process parameters during the development phase, we can significantly shorten the development cycle.

Industry Experience and Achievements

- 30 years of technical accumulation: Over 300 precision molds delivered.
- Cross-industry applications: Covering fields with high precision requirements such as life sciences consumables and medical devices.
- 50-person maintenance team: 70% of members have more than 10 years of mold maintenance experience.

Their work ensures that our precision molds possess excellent high-repeatability accuracy, durability, and short molding cycles.

01 Material

Procurement of steel from sweden, Germany, and Japan provides better mold polishing performance and higher product flatness

02 Design

Unique cooling and exhaust system

03 HotRunner

Select the most suitable hot runner system based on the product characteristics of thin walls, high transparency,multi-cavity, and short cycle times

04 Technique

Use professional analysis software Moldflow for analysis

05 Flexibility

Offer customized solutions for clients

Raw Material Assurance

We focus on the research of polymer materials and have mastered modification techniques. We possess extensive experience in the performance and application of materials such as PP and PC. We also have rich application experience in the fields of environmentally-friendly plastics, medical-grade plastics, and specialty functional polymer materials.

Specific materials, physical and chemical analysis – Incoming material control

Nest implements strict control measures for supplier approval and raw material/packaging material approval. We conduct detailed material, physical, and chemical analysis on raw materials. Our laboratory staff possesses deep expertise, and the laboratory is well-equipped to perform physical and chemical analysis, such as viscosity, residual moisture, and density, to meet the personalized needs of our clients.

The company ensures that all raw materials/packaging materials meet product technical requirements through the following steps:

- Supplier questionnaire survey
- Supplier on-site audit
- Raw material/packaging material report review
- Raw material/packaging material performance validation
- Raw material/packaging material batch inspection

The implementation of these measures guarantees the stability of the supply chain and the quality of the products. This section will also list Nest's relevant statements on the control of raw materials and packaging materials:

Raw Material Compliance Statement (ROHS, REACH)

The raw material particles used in Nest's reusable pen injectors have relevant reports provided by the manufacturer, complying with ROHS and REACH regulations, including but not limited to ABS, PC, PP, etc.

ROHS: Nest strictly adheres to the European Union regulation “Directive on the restriction of certain hazardous substances in electrical and electronic equipment” (2011/65/EU) (ROHS). This standard controls the levels of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers in products.

REACH: Nest strictly follows the European Union regulation “Registration, Evaluation, Authorization, and Restriction of Chemicals” (2006/1907) (REACH) to control substances of very high concern (SVHC) in raw materials.

Quality Assurance

Production Environment

Class 100,000 and Class 10,000 Cleanroom Certification

NEST has multiple cleanrooms that comply with ISO14644 Class 7 and Class 8 standards, and these rooms undergo periodic third-party monitoring to ensure compliance with product manufacturing and packaging requirements. Cleanroom certification reports can be obtained through our official website or by contacting us via email.

Cleanroom Environmental Control Methods

NEST follows the ISO14644 requirements and our company' s procedures for monitoring cleanroom environments, including dust particles, airborne bacteria, sedimentation bacteria, air exchange rates, temperature and humidity, pressure differential, and compressed air. This ensures that our cleanroom environments meet regulatory standards.

Aseptic Testing Laboratory Qualification

NEST owns a Biosafety Level 2 (BSL-2) aseptic testing laboratory, where the production environment is regularly tested in accordance with cleanroom environmental testing protocols to ensure both the safety and reliability of the environment and that the final product meets customer requirements.

Purified Water System Validation

NEST is equipped with multiple purified water systems used for cleaning all cleanroom surfaces, cleanroom attire, and work tools. This ensures that the water quality in the cleanrooms is maintained. Periodic testing is conducted on the purified water for properties including pH, ammonia, conductivity, nitrate, nitrite, oxidizable substances, non-volatile substances, heavy metals, and microbial limits. The system ensures that the purified water complies with the Chinese Pharmacopoeia (2020 edition) or the European Pharmacopoeia (2020 edition) standards.

Sterilization Center

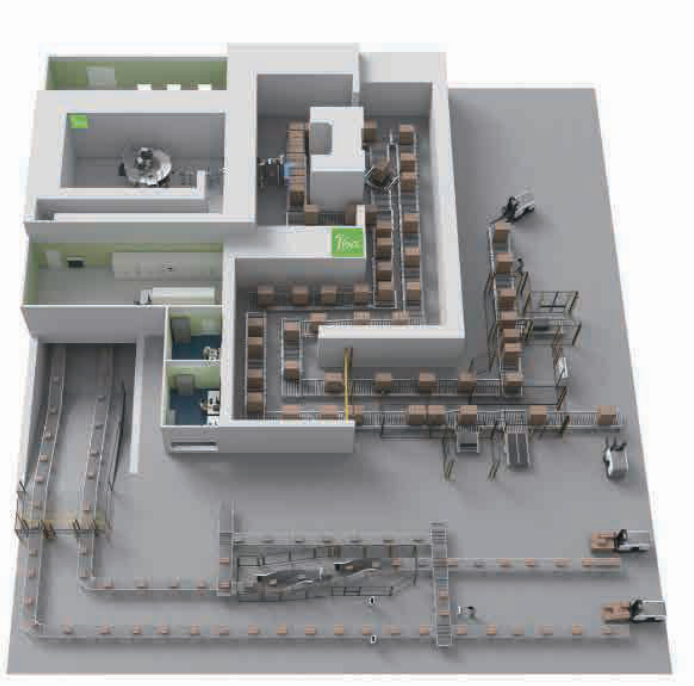
The company owns internationally leading sterilization equipment, including one IBA Rhodotron® TT200 electron accelerator (EBeam: 10MeV, 5mA, 50KW) and one IBA Rhodotron® TT300 dual-ray accelerator (EBeam: 10MeV, 8mA, 80KW; X-ray: 5/7MeV, 140/190KW). These high-power accelerators offer multiple sterilization methods and provide a wide range of irradiation services.

We offer professional sterilization, disinfection, material modification, and irradiation processing services for manufacturers of medical products, pharmaceuticals, health products, raw materials, food, pet products, cosmetics, polymer materials, and more.

Rhodotron® TT300

Equip parameters:

Main parameters	index
X-ray:	
Energy	5/7Mev
Power	140/190KW
Scanning Width	220cm
Non-uniformity	≦±5%
Beam Down Speed	0.5-4m/min
E-Beam:	
Energy	10Mev
Power	80KW
Flux Density	8mA
Scanning Width	100cm
Non-uniformity	≦±5%
Beam Down Speed	2-12m/min



Global Warehousing and Logistics Capabilities

Subsidiary Distribution

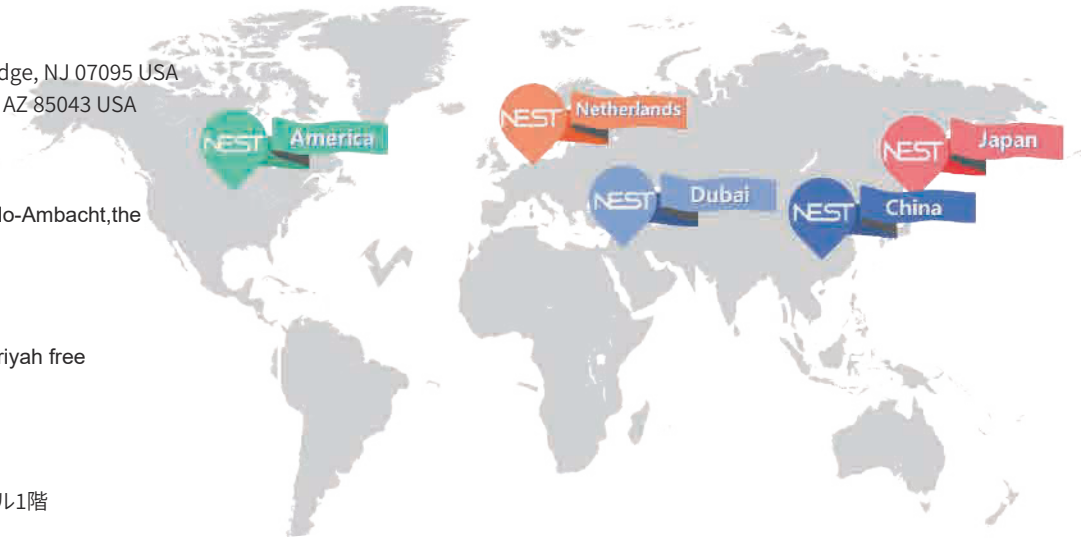
The company is committed to providing first-class products and services to global customers. We have established subsidiaries in the United States, the Netherlands, the UAE, and Japan to support our brand’ s expansion and development in international markets. Our U.S. subsidiary has been deeply engaged in the overseas market for over a decade. With the completion of a newly purchased warehouse in the western United States, we are now successfully providing integrated services for storage, transportation, and sales to our customers.

USA:
USA east: 3 Convery Blvd, Woodbridge, NJ 07095 USA
USA west: 641 S 53rd Ave, Phoenix, AZ 85043 USA

Europe:
Ecologieweg 10, 3343LM Hendrik-Ido-Ambacht,the Netherlands

Middle east:
Warehouse LV-22D,phase 2 of hamriyah free zone,Sharjah, UAE

Japan:
横浜市都筑区池辺町3513番地B&Iビル1階



Supply Chain Stability and Lead Time

To ensure supply stability and timely delivery, NEST manages the supply chain and lead time through the following measures:
Long-Term Supply Contracts: Signing long-term supply contracts with customers to ensure stable supply over a defined period.
Safety Stock: Maintaining a certain amount of safety stock during production to address unforeseen circumstances.
Timely Scheduling: Adjusting production schedules based on customer orders and inventory status to ensure on-time delivery.

Traceability

NEST provides the following methods to trace the production and transportation process of products:
Batch Information: Information for each product batch is recorded in the form of batch numbers, allowing traceability of key process inspection data and test results. Customers can trace the production status of the product using this information.
Production Records: In NEST’ s production process, data from each process step, including raw materials, injection molding, and other product processing steps, are retained. This data can be used to trace the production status of the product.
Sample Retention: A sample is retained from each batch of products, allowing customers to trace the production status of the product.
Transportation Process Inspection: In addition to the production process, NEST also inspects the product during transportation to ensure that it has not been damaged or experienced quality issues during transit.

Shelf Life

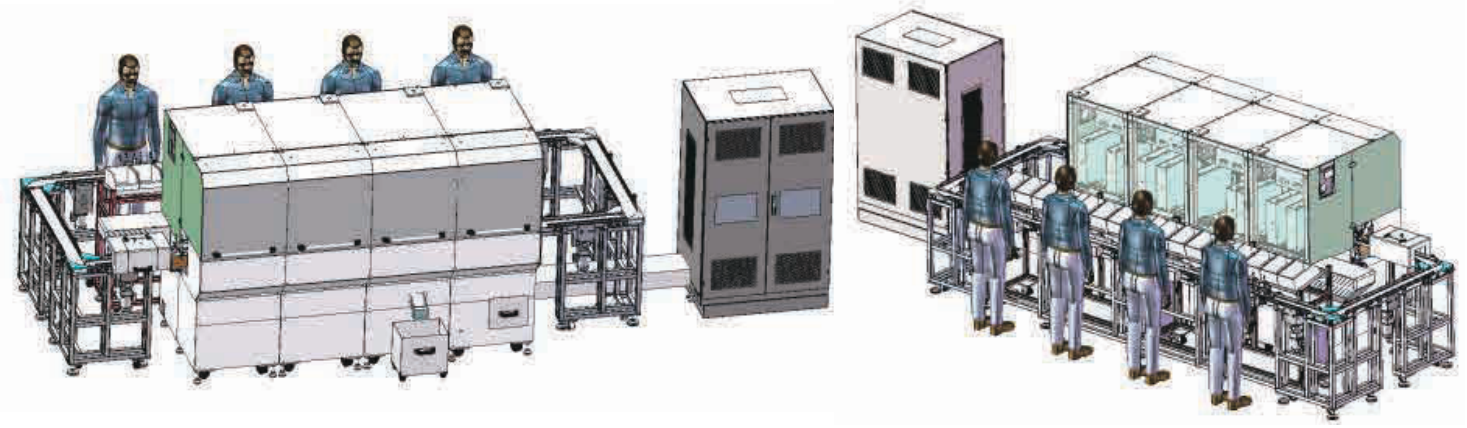
NEST determines the shelf life of its products by conducting accelerated aging tests according to YY/T 0681.1-2018 or ASTM F1980 standards. For specific details on the testing content, please refer to the shelf life testing section of the product tests. The shelf life is calculated from the time of product production, with the batch number specified in the COA/COC of the accompanying NEST product as the reference. The general shelf life of the product can typically be found in the COA/COC and the product technical documents on the official website.
Unless otherwise stated, the general storage conditions for NEST medical devices and pharmaceutical packaging materials are relative humidity not exceeding 80%, at room temperature (10-30°C), and in a light-protected environment. During transportation, the products should be protected from mechanical impact or contact with sharp objects, avoid direct sunlight and rain, and ensure the packaging remains intact and the product is not contaminated.

Supporting Services

Pen Injector Assembly Line Turnkey Solutions Providing Modern ——Manufacturing Solutions for the Pharmaceutical and Healthcare Industry Automated Assembly System

Automated Assembly System

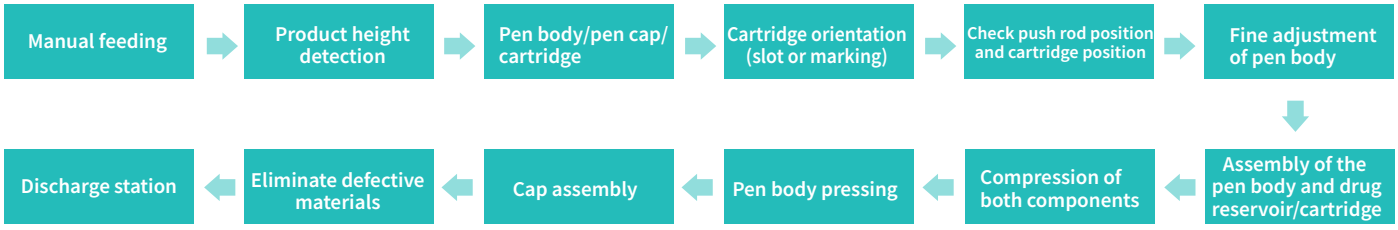
We plan, procure, or develop automated assembly systems tailored to meet the specific requirements of our clients, designed for particular components. These systems include automated testing systems, rotary table systems, vision systems, linear systems, robots for inserting and removing parts, packaging systems, pre-production equipment, and pharmaceutical assembly systems.



The equipment is designed to assemble the pen core frame, pen cap, pen body, and cartridge into a complete pre-filled pen injector.

- The highly flexible and efficient standardized modular design is at the core of the system. It uses pre-designed, interchangeable standardized components, allowing for rapid and precise configuration and adjustments based on the production needs of different products. This greatly improves the adaptability and flexibility of the production line, significantly reducing the time and costs required to change product lines.
- Main drive force: Cam drive mechanism. The cam structure is renowned for its precise motion control and reliable synchronization performance, ensuring the accuracy and efficiency of the assembly process. It helps to reduce errors and scrap rates, enhancing the overall production quality.
- Multiple testing stations are used to ensure the consistency of the final product through various methods such as pressure and visual checks.Continuous quality monitoring and feedback mechanisms help users promptly identify and resolve potential issues, preventing negative impacts on subsequent assembly steps or the final product.

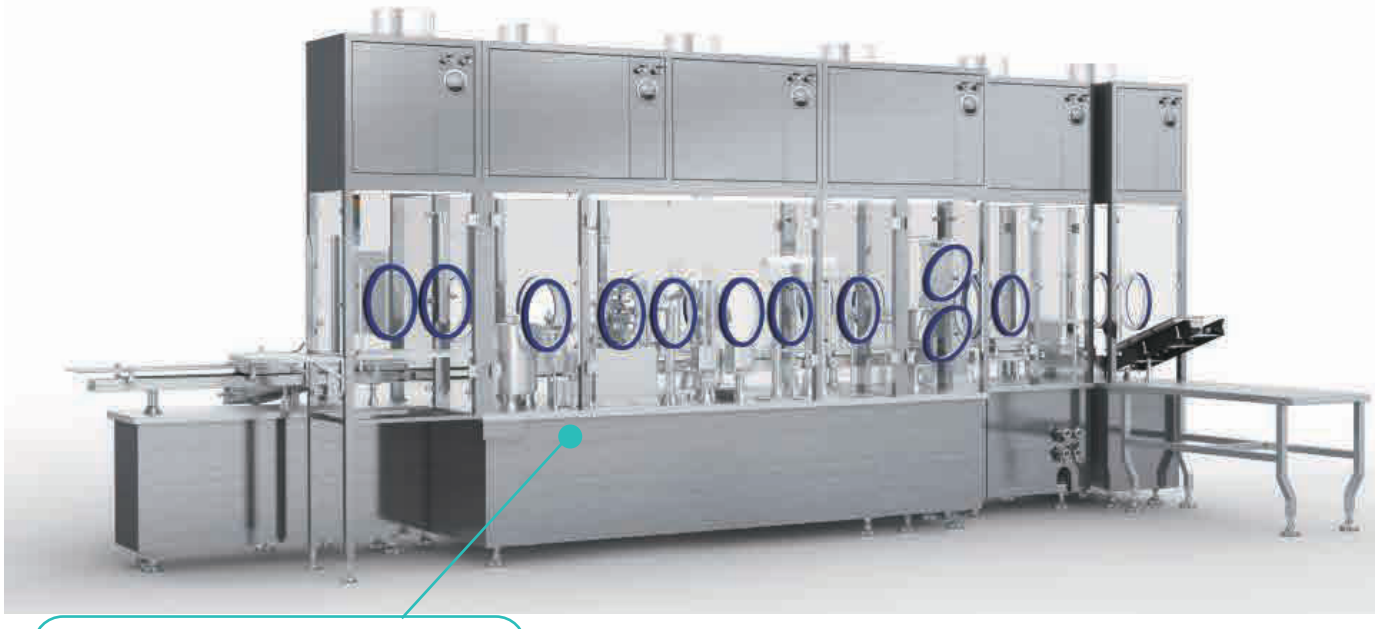
Flowchart



Cartridge Automatic Filling System and Related Products

2 Filling Ports Cartridges Automatic Filling System

5 Filling Ports Cartridges Automatic Filling System



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