Sterility Test Isolator

ZHEJIANG TAILIN BIOENGINEERING CO., LTD

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Integrated Solution Provider in Life Science

Zhejiang Tailin Bioengineering (Tailin), an integrated solutions provider in the life sciences, was established in 2002. The company operates across a range of vital sectors, including biotechnology, precision medicine, pharmaceutical engineering, radiopharmaceuticals, food safety, and advanced materials.

Our core strength lies in developing customized solutions tailored precisely to our clients' needs. Our products are widely applied in pharmaceutical companies, labs, cleanrooms, hospitals, and research institutes. Notable offerings include aseptic isolators, glove integrity testers, VH2O2 decontamination systems, sterile pass boxes, sterility test pumps & canisters, filtration membranes, TOC analyzers, filter integrity testers, and beyond.

Our team consists of nearly 1,000 employees, including 200 R&D engineers. We hold over 300 national patents and actively participate in drafting national and industry standards to advance our field.

We have strong partnerships with pharmaceutical companies and laboratories in over 50 countries. Tailin aims to continue growing and improving our services for our customers while contributing to health and safety.

Tailin Brand: Established in 1993
Tailin Bioengineering(Tailin): Established in 2002
Tailin IPO: 2020 (Stock Code: SZ300813)
Tailin Sictech: a subsidiary of Tailin, responsible for overseas business

HTY Series

The Sterility Test Isolator is a custom-designed cGMP Class A/ISO 5 isolator system, specifically engineered to provide the safest and most ergonomic working conditions for quality control operations. Tailin hard-wall laminar flow sterility test isolator HTY series features a rigid structure made of stainless steel and tempered glass, creating a dynamic Class A internal environment. Operations within the isolator are conducted using gloves, available in two versions: a thick, tear-resistant model and a thin, highly tactile option. The system incorporates a Siemens Programmable Logic Controller (PLC) for fully automated control of pressure and airflow volume and includes a pressure loss alarm function. Comply with GMP, USP, EP.

+ Built-in Sterility Test Pump + Built-in Vaporized Hydrogen Peroxide Sterilization System + Customized

Application

For GMP inspections of sterile pharmaceuticals, including sterile preparations and sterile active pharmaceutical ingredients.

For sterility tests, sampling, weighing, dispensing, etc.

The sterility test, aseptic preparation and filling could be conducted in an isolator located whithin Class C/D, according to EU GMP Annex 1 and PIC/S<Recommendation on Sterility Testing> 8.1.1

Sterility Test Isolator

Features

Sterile Assurance

HTY series isolators ensure the highest air quality within the isolation environment:

- Engineering filtration system comprising H14 High-Efficiency Particulate Air (HEPA) filters.
- The integration of the latest generation of vaporized hydrogen peroxide sterilizers developed by Tailin, coupled with precise hydrogen peroxide gas concentration/saturation control technology, which rapidly steriizes the internal environment of the chamber, guaranteeing a sterile environment during sampling processes.
- Inflatable seals made of GMP-approved silicone ensure the tightness of the chamber.
- A fully enclosed physical barrier avoids direct contact between operators and products, addressing the issue of microbial contamination.
- Real-time monitoring of settling microorganisms, temperature, humidity, pressure, and airspeed within the chamber ensures the production environment remains continuously controlled.

Automatic Leak Testing

HTY series isolator is equipped with an automatic leak testing system that individually tests each chamber for leaks using the pressure decay method as described in international standard ISO 10648-2. Leakage rate is less than 0.5% /vol/hour under 2 times working pressure test .

Glove Integrity Testing

HTY series isolators are equipped with an integrated automated glove leak testing system (GIT Series) which performs an independent leak test on each glove installed on the isolator system according to the positive pressure decay method described in the international standard ISO 14644-7. It detects holes as small as 100μm in diameter.

Data Management

Comply with 21 CFR Part 11 electronic records and signature requirements.

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Model Selection

Model	Description	Overall Dimensions	Operating Space	Inner Pass box
HTY-1250G2	Operating chamber with Pass box-2Gloves	2300x870x2420mm	1240x680x700mm	600x550x700mm
HTY-1650G3	Operating chamber with Pass box-3Gloves	2700x870x2420mm	1640x680x700mm	600x550x700mm
HTY-1800G4	Operating chamber with Pass box-4Gloves	2850x870x2420mm	1790x680x700mm	600x550x700mm
HTY-1800G8	Operating chamber with Pass box-8Gloves(Double Side)	2650x1240x2420mm	1750x1200x650mm	600x650x600mm
HTY-1250AG2	Operating chamber-2 Gloves	1675x870x2420mm	1250x680x700mm	NIL
HTY-1650AG3	Operating chamber-3 Gloves	2075x870x2420mm	1640x680x700mm	
HTY-1800AG4	Operating chamber-4 Gloves	2225x870x2420mm	1790x680x700mm	
HTY-1800AG8	Operating chamber-8Gloves (Double Side)	2370x1240x2420mm	1750x1200x650mm	

Size Can Be Customized:

*Some models

HTY-1650AG3

HTY-1650AG3(RTP)

HTY-1250AG2

HTY-1800G4

HTY-1800AG4

HTY-1800G8

Technical Parameters

Power Supply: AC380V/50Hz	Max.Power: 3000W-4000W
Cleanliness: GMP Class A	Chamber Pressure Range: From -80Pa to +80Pa
Airflow Direction: Laminar flow	Velocity: 0.36~0.54m/s
Built-in Sterility Test Pump: 1 or multiple	Compressed Air Supply: 0.4MPa-0.6MPa clean and dry
Killing Rate: ≥log6	Noise: ＜75dB(A) when in pressure hold stage
Touch Screen: 12" Tablet PC	Leakage Rate: ＜ 0.5% /vol/hour under 2 times working pressure test
Vaporized Hydrogen Peroxide Residual Concentration: ＜1ppm	Cabin Illumination: 500 lux, LED light source

Optional Accessories of Isolator

Half-Suit Integrity Tester

Glove Integrity Tester

Air Sampler

Particle Counter

H_2O_2 Concentration Sensor

RTP Integrity Tester

Buit-in Sterility Test Pump

Barcode Printer

Barcode Scanner

Video Monitor

Validation & Serivices

- DQ/IQ/OQ Documents
- Samples Safety Test
- Chemical Indicators(CIs)
- Biological Indicators(BIs)
- H_2O_2 Residue Test
- SAT/FAT and Training
- Bio-decontamination Effectiveness Report
  - BIs incubation result
  - CIs indication result
  - Bio-decontamination parameters and process data
  - Layout and place points of BIs and CIs