



## Sterilization Monitoring and Validation



Zhejiang Tailin Scitech Co., Ltd  
 Fully owned subsidiary of Zhejiang Tailin Bioengineering Co., Ltd  
 No.2930 Nanhuan Road, Binjiang, Hangzhou, Zhejiang, China.

TEL:0086-571-86589087      FAX:0086-571-86689998  
 E-MAIL: marketing@tailingood.com      WEB: www.tailinscitech.com



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# Sterilization Monitoring and Validation

## Types of Biological Indicators

Tailin provides biological indicators suitable for sterilization (disinfection) by steam, hydrogen peroxide, dry heat, ethylene oxide, ozone and so on. It can provide carrier-type, spore suspension-type and self-contained indicator according to the demand. Customized services for spore concentration and D-value of biological indicators are available.

## Regulations

Biological indicators are the ideal process indicators that directly monitor the lethality of a given sterilization process. Tailin's biological indicators meet the requirements of ISO 11138, GB18281, GMP, PDA TR51, FDA 510k and Pharmacopoeia (USP, EP, ChP). The spores used are traceable and the test report includes spore concentration, D-value, and other relevant data.

## Applications

Biological indicators are suitable for pharmaceutical enterprises, medical device industries, CDC, biosafety laboratories and so on. Tailin's biological indicators are of reliable quality and complete types, and can provide professional technical support for users.

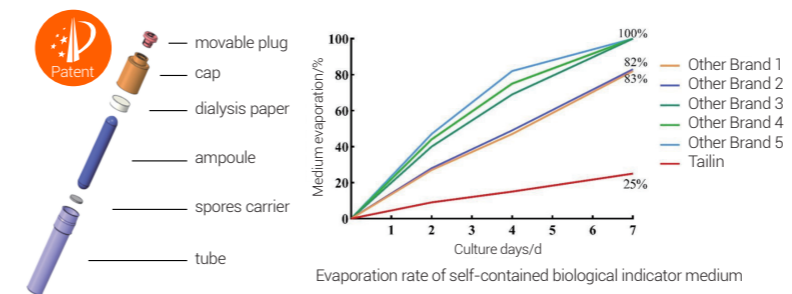


# Sterilization Monitoring and Validation

## Self-Contained BIs for Autoclave Steam

Patented design structure, effective control of medium evaporation during cultivation, compliance with GMP requirements.

The medium is resistant to sterilization up to 134 °C.



## Spore Suspension for Moist Heat

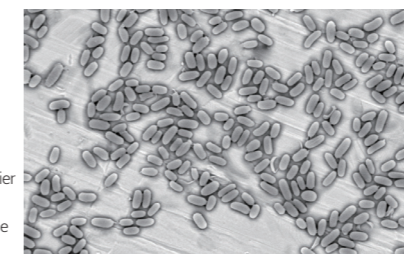


Self-developed medium formula, sterilized at 134 °C for 2h without fading.

Provide products with suitable parameters for different sterilization time at 121°C. Customized service for spores concentration and D value.

## Self-Contained BIs for Vaporized Hydrogen Peroxide

Suitable for sterilization validation of vaporized & atomized hydrogen peroxide. Mature spore preparation process, purity of spores is higher than 99%. Patented design structure, easy to use, high temperature resistant culture.



Scanning electron microscopic observation of hydrogen peroxide sterilized biological indicator carriers



## Biological Indicators

### Biological Indicators for Autoclave Steam

They are used to confirm the performance of steam sterilization equipment, develop and establish steam sterilization processes, and re-validation of the steam sterilization equipment. They are suitable for pharmaceutical enterprises, medical device industries, CDC, biosafety laboratories and other fields.

- + Self-contained BIs with a patented structure, less than 10% evaporates of incubation
- + Color-changing medium, 48h for accurate results
- + Medical packaging dialysis paper avoid external contamination and allows steam penetration
- + Selected carriers for easy microbial elution and count



Type	Catalog No.	Species	Population	Storage	Shelf Life	Packing
Self-contained	SS6-105	<i>Bacillus subtilis</i> ATCC6633	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pcs/pkg
	SS6-115	<i>Bacillus subtilis</i> ATCC35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pcs/pkg
	SS6-121	<i>G.stearotherophilus</i> ATCC7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pcs/pkg
Paper strip	SP6-115	<i>Bacillus subtilis</i> ATCC35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pcs/pkg
	SP6-121	<i>G. steaotherophilus</i> ATCC7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pcs/pkg
	SP3-121*	<i>G. steaotherophilus</i> ATCC7953	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-25°C	12Months	50pcs/pkg

### Spore Suspension for Moist Heat

Spore suspensions are used to monitor the sterilization performance of various moist heat sterilizers, particularly suitable for monitoring the internal sterilization of liquid products.

- +Color-changing medium, 48h for accurate results
- +High strength ampoules, not easily broken
- +Special production process, stable performance of spores during shelf life
- + The capsule vial is more compact, suitable for monitoring the sterilization effect of specific materials such as medical devices



Type	Catalog No.	Species	Population	Storage	Shelf Life	Packing
Ampoule	ML6-115A	<i>Bacillus subtilis</i> ATCC35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg
	ML6-121A	<i>G.stearotherophilus</i> ATCC7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg
	ML3-121A*	<i>G. steaotherophilus</i> ATCC7953	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-8°C	12Months	50pcs/pkg
	ML6-115AS	<i>Bacillus subtilis</i> ATCC35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg
	ML6-121AS	<i>G. steaotherophilus</i> ATCC7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg
Capsule vial	ML6-115T	<i>Bacillus subtilis</i> ATCC35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg
	ML6-121T	<i>G. steaotherophilus</i> ATCC7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg
	ML3-121T*	<i>G. steaotherophilus</i> ATCC7953	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-8°C	12Months	50pcs/pkg

### Biological Indicators for Vaporized Hydrogen Peroxide

Specially designed to meet the needs of the pharmaceutical, food, and medical device industries using vaporized & atomized hydrogen peroxide decontamination.

- + Self-contained BIs, easy to use, press for instant inoculation
- + Patented structure, less than 10% evaporates of incubation
- + Tyveke® packaged to meet the requirements for hydrogen peroxide penetration while avoiding external contamination
- + Waterproof to ensure safety and effectiveness in high humidity environments



Type	Catalog No.	Species	Population	Storage	Shelf Life	Packing
Self-contained	HS4-600	<i>G.stearotherophilus</i> ATCC12980	1x10 <sup>4</sup> ~5x10 <sup>4</sup>	2-8°C	12Months	30pcs/pkg
	HS6-600	<i>G.stearotherophilus</i> ATCC12980	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	30pcs/pkg
	HS3-600*	<i>G.stearotherophilus</i> ATCC12980	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-8°C	12Months	30pcs/pkg
Stainless steel strip	HP4-600	<i>G.stearotherophilus</i> ATCC12980	1x10 <sup>4</sup> ~5x10 <sup>4</sup>	2-8°C	12Months	50pcs/pkg
	HP6-600	<i>G.stearotherophilus</i> ATCC12980	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg

### Biological Indicators for Hydrogen Peroxide Low Temperature Plasma

They are used to monitor the sterilizing effect of hydrogen peroxide plasma sterilizers, which are widely used in hospitals, medical device industries and other fields.

- + Patented structure, ensure hydrogen peroxide penetration and avoid false positives
- + Effective control of medium evaporation during incubation
- + Color-changing medium, 48h for accurate results
- + Selected carriers for easy counting



Type	Catalog No.	Species	Population	Storage	Shelf Life	Packing
Self-contained	PS6-023	<i>G. steaotherophilus</i> ATCC7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pcs/pkg

Note: "\*" is for customized models. For more species and concentration customized options, please contact Tailin.

## Biological Indicators for Ethylene Oxide

They are used to monitor EO sterilization effectiveness, and re-validation of the EO sterilization equipment, which are widely used in pharmaceuticals, medical device industries and other fields.

- + Self-contained BIs with a patented structure, less than 10% evaporates of incubation
- + Color-changing medium, 48h for accurate results
- + Medical packaging dialysis paper avoid external contamination and allows EO penetration
- + Selected carriers for easy microbial elution and count



Type	Catalog No.	Species	Population	Storage	Shelf Life	Packing
Self-contained	ES6-600	<i>Bacillus atrophaeus</i> ATCC9372	1x10 <sup>6</sup> ~5x10 <sup>7</sup>	2-25°C	12Months	50pcs/pkg
	ES3-600*	<i>Bacillus atrophaeus</i> ATCC9372	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-25°C	12Months	50pcs/pkg
Paper strip	EP6-600	<i>Bacillus atrophaeus</i> ATCC9372	1x10 <sup>6</sup> ~5x10 <sup>7</sup>	2-25°C	12Months	300pcs/pkg
	EP7-600*	<i>Bacillus atrophaeus</i> ATCC9372	1x10 <sup>7</sup> ~5x10 <sup>7</sup>	2-25°C	12Months	50pcs/pkg

## Biological Indicators for Gas Fumigation

They are suitable for monitoring the effectiveness of space sterilization such as ozone, formaldehyde and chlorine dioxide. Provided with *staphylococcus albus* 8032 and *bacillus atrophaeus* ATCC 9372 as species. Widely used in pharmaceuticals, medical device industries and other fields.

- + Stainless steel sheet carrier, effectively avoiding false positives
- + Tyvek® packaged to meet the requirements for sterilization gas penetration while avoiding external contamination



Type	Catalog No.	Species	Population	Storage	Shelf Life	Packing
Stainless steel strip Paper strip	GP3-9372	<i>Bacillus atrophaeus</i> ATCC9372	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-8°C	12Months	50pcs/pkg
	GP6-9372	<i>Bacillus atrophaeus</i> ATCC9372	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pcs/pkg
	GP3-8032	<i>Staphylococcus albus</i> 8032	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	≤-18°C	6Months	50pcs/pkg

## Biological Indicators for Dry Heat

They are used to confirm the performance of dry heat sterilization equipment, and monitor dry heat sterilization effectiveness. Widely used in pharmaceuticals, scientific institution and other fields.

- + High strength ampoules, not easily broken
- + Carriers resistant to high temperature sterilization



Type	Catalog No.	Species	Population	Storage	Shelf Life	Packing
Ampoule	DP6-160	<i>Bacillus atrophaeus</i> ATCC9372	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pcs/pkg

## Culture Medium



Type	Catalog No.	Applicable Products	Storage	Shelf Life	Packing
<i>G. stearothermophilus</i> medium	BPDP-2.5	SP6-121, HP4-600, HP6-600	2-8°C	12Months	50pcs/pkg
<i>Bacillus atrophaeus</i> medium	MTSB-2.5	EP6-600, DP6-160, GP3-9372, GP6-9372	2-8°C	12Months	50pcs/pkg
<i>Tryptic soy broth</i> liquid medium	TSB-2.5	GP3-8032, SP6-115	2-8°C	12Months	50pcs/pkg

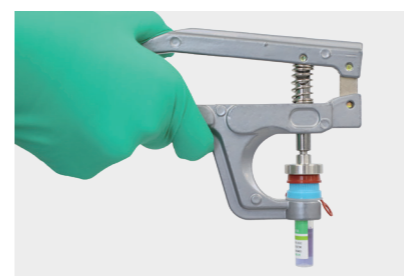
## Spore Suspensions



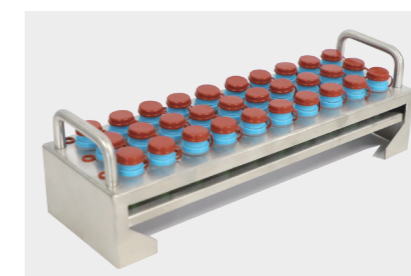
Type	Catalog No.	Applicable Products	Storage	Shelf Life	Packing
<i>G. stearothermophilus</i> ATCC7953	G8-7953	Autoclave steam sterilization, etc.	2-8°C	12Months	10mL/vial
<i>G. stearothermophilus</i> ATCC12980	G8-12980	Hydrogen peroxide sterilization, etc.	2-8°C	12Months	10mL/vial
<i>Bacillus atrophaeus</i> ATCC9372	B8-9372	EO/dry heat/ozone sterilization, etc.	2-8°C	12Months	10mL/vial
<i>Bacillus subtilis</i> ATCC35021	B8-35021	Low temperature pressure steam sterilization, etc.	2-8°C	12Months	10mL/vial

Note: Spore concentration of spore suspensions ≥ 10<sup>6</sup>cfu/ml

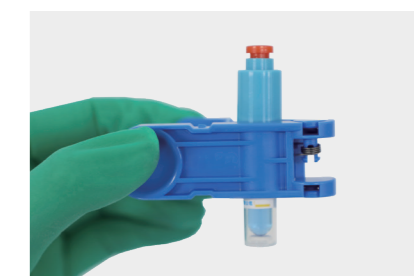
## Accessories of BIs



Hand pressure plier of self-contained BIs for hydrogen peroxide



Test tube stand of self-contained BIs for hydrogen peroxide



Clamp of self-contained BIs for autoclave steam/hydrogen peroxide low temperature plasma/EO

## Chemical Indicators

CIs are mainly used to monitor various sterilization processes and confirm that the sterilization conditions meet the requirements through color changes.

CIs have special sensitivity to specific environmental factors (e.g., temperature, humidity chemicals, etc.). CIs will change color according to these factors to assist in determining the effectiveness of the sterilization.

Tailin's CIs for monitoring the sterilization of steam, hydrogen peroxide and ethylene oxide meet the requirements of GB 18282.1/ISO 11140 and other relevant standards. Used together with BIs to ensure the safety of sterilization.

**Steam Sterilization Chemical Indicator**

Initial Yellow  Turns Black  Indicator →

\*Indicator changes from yellow to black after sterilization

**Vapor Hydrogen Peroxide Chemical Indicator**

Initial Green  Turns Yellow  Indicator →

\*Indicator changes from green to yellow after sterilization

**Ethylene Oxide Sterilization Chemical Indicator**

Initial Red  Turns Blue  Indicator →

\*Indicator changes from red to blue after sterilization

Type	Applications	Storage	Shelf Life	Packing
CIs for Hydrogen Peroxide	Used for chemical monitoring of sterilization effect in sterility test isolators, transfer chambers, hydrogen peroxide plasma sterilizers, and vaporized/atomized hydrogen peroxide sterilizers	2-25°C	12Months	200pcs/pkg
CIs for Autoclave Steam	Used for chemical monitoring of sterilization effect in pressure steam sterilizer, etc.	2-25°C	12Months	200pcs/pkg
CIs for Ethylene Oxide	Used for chemical monitoring of sterilization effect in EO sterilization cabinet, etc.	2-25°C	12Months	200pcs/pkg

Difference	Chemical Indicators	Biological Indicators
Principle	Assists in determining the sterilization effect based on the color changes that occur in the CIs when exposed to the external environment (temperature, chemical substances)	Determine the sterilization effect based on the survival of microorganisms
Accuracy	There is some error and the killing of microorganisms cannot be evaluated	The most intuitive indicator
Reaction Time	The results can be observed at the end of the sterilization process	A certain incubation period is required

## B-D Test Pack

The B-D test pack, also referred to as the Bowie-Dick test pack, is mainly utilized to assess the cold air removal efficiency and steam penetration effectiveness of pulsating vacuum steam sterilizers. The performance compliance of the sterilizer is determined by observing whether the test paper within the B-D test pack.



Type	Model	Storage	Shelf Life	Packing
B-D Test Pack	KC2159	Temp 2-25°C, RH < 50%	12Months	20pcs/pkg
B-D Test Pack	KC2160	Temp 2-25°C, RH < 50%	12Months	20pcs/pkg
B-D Early Warning Test Pack	KC2159-5	Temp 2-25°C, RH < 50%	12Months	20pcs/pkg
B-D Early Warning Test Pack	KC2160-5	Temp 2-25°C, RH < 50%	12Months	20pcs/pkg

## Biological Indicator Evaluation Resister

### BIER-S100

#### Pressure Steam Sterilization BIER



- + Intelligent operation; one-click automatic water filling, sterilization, and exhaust
- + Data authority, traceability, and real-time observation to verify or determine the sterilization situation
- + Safe and reliable; door opening protection, automatic pressure relief, temperature grading, negative pressure airtightness test procedures, multi-level management authority settings
- + High Stability
- + Flexible adjustments to customize the program, one-click generation of the test report

#### Technical Parameters

Sterilization Method: Pressure Steam Sterilization	Temperature Range: 110-145°C	Leakage Rate: ≤0.1 kPa/min
Sterilization Target: Biological Indicator	Vacuum: 2 kPa	Non-condensable Gas: ≤2.5%
Sterilization Chamber Volume: 5L	Time to Vacuum: <30 s	Superheated Steam: ≤5°C
Dimensions: 175.0 x 78.0 x 95.0 cm	Come-up Period: ≤8 s	Steam Quality: ≥0.98
Power Supply: AC 380V/50Hz	Sterilization Temperature Deviation: ±0.4°C	Sterilization Curve: Yes
Weight: 150 kg	Come-down Period: ≤5 s	Test Report: Yes
Electric Heating Power: 9KW	Time Accuracy: ±1 s	Three-level Management: Yes

## BIER-VH100

### Vaporized Hydrogen Peroxide Sterilization BIER



- + Intelligent operation; one-click automatic, sterilization, and exhaust
- + Data authority, traceability, and real-time observation to verify or determine the sterilization situation
- + Safe and reliable; door opening protection, automatic pressure relief, temperature grading, negative pressure airtightness test procedures, multi-level management authority settings
- + High Stability
- + Flexible adjustments to customize the program, one-click generation of the test report

#### Technical Parameters

Hydrogen Peroxide Concentration Monitoring: TD-LAS laser sensor Water Gas Concentration accuracy: $\pm 0.3$ mg/L Power Supply: 380VAC/50HZ		
Hydrogen Peroxide Concentration Range: 1~10mg/L	Sterilization Temperature Range: 45 C ~60 C	Power: 5KW
Hydrogen Peroxide Concentration Accuracy: $\pm 0.3$ mg/L	Pressure Range: 0.01kPa~102kPa	Dimensions: 112 x 105 x183 (cm)
Water Vapor Concentration Monitoring: TD-LAS laser sensor	Negative Pressure Leakage Rate: $\leq 5$ Pa/min	Weight: 700kg
Water Content Probe: 1~20mg/L	Maximum Single Test Quantity: 24 self-contained BIs / 24 carrier-type (sheet) BIs	
Compatible Indicator Types: compatible with both self-contained and carrier (sheet) biological indicator tests		
Management Authority: three levels of management authority with GMP management requirements		

## BIER-EO100

### Ethylene Oxide Sterilization BIER



- + Intelligent operation; one-click automatic heating, leak detection,sterilization, residue discharge
- + Data authority, traceability, and real-time observation to verify or determine the sterilization situation
- + Safe and reliable; door opening protection, automatic pressure relief, temperature grading, negative pressure airtightness test procedures, multi-level management authority settings
- + High Stability
- + Flexible adjustments to customize the program, one-click generation of the test report

#### Technical Parameters

Monitoring Method: Sensors from the US brand	Concentration Decline Period: $\leq 10$ s	Power Supply: 380VAC/50HZ
Sterilizer Concentration: 100~1200mg/L	Time to Vacuum: $\leq 60$ s	Power: 5KW
Sterilization Temperature: 29 C ~65 C	Leakage Rate: $\leq 0.13$ kPa/min	Dimensions: 112 x183 x 105 (cm)
RH: 30%~80%	Single Sterilization Quantity: 20 pcs	Weight: 700kg
Pressure Range: 4~20kPa	Electronic Signature: Yes	Test Report: Yes
Concentration Rising Period: $\leq 10$ s	Sterilization Curve: Yes	
Management Authority: three levels of management authority with GMP management requirements		