



## Biological Indicators

# Sterilization Validation Solutions

## 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

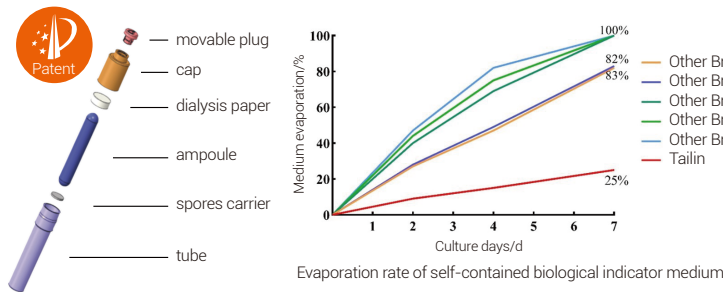
Biological indicators are suitable for pharmaceutical enterprises, medical device industries, CDC, biosafety laboratories and so on. Tailin's biological indicators are of reliable quality and complete types, and can provide professional technical support for users.



# Popular Biological Indicators

## 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 135 °C.



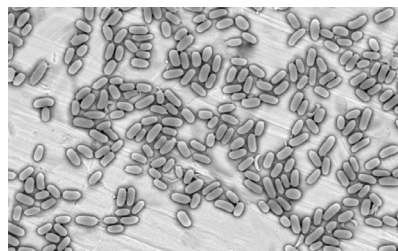
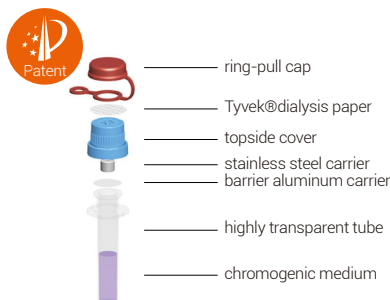
## Spore Suspension for Moist Heat



Self-developed medium formula, sterilized at 121 °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	SS6-115	<i>Bacillus subtilis</i> ATCC35021	$1 \times 10^6 \sim 5 \times 10^6$	2-25°C	12Months	50pc/pkg
	SS6-121	<i>G.stearotherophilus</i> ATCC7953	$1 \times 10^6 \sim 5 \times 10^6$	2-25°C	12Months	50pc/pkg
Paper strip	SP6-115	<i>Bacillus subtilis</i> ATCC35021	$1 \times 10^6 \sim 5 \times 10^6$	2-25°C	12Months	50pc/pkg
	SP6-121	<i>G. steaotherophilus</i> ATCC7953	$1 \times 10^6 \sim 5 \times 10^6$	2-25°C	12Months	50pc/pkg
	SP3-121*	<i>G. steaotherophilus</i> ATCC7953	$1 \times 10^3 \sim 5 \times 10^3$	2-25°C	12Months	50pc/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	$1 \times 10^6 \sim 5 \times 10^6$	2-8°C	12Months	50pc/pkg
	ML6-121A	<i>G.steaotherophilus</i> ATCC7953	$1 \times 10^6 \sim 5 \times 10^6$	2-8°C	12Months	50pc/pkg
	ML3-121A*	<i>G. steaotherophilus</i> ATCC7953	$1 \times 10^3 \sim 5 \times 10^3$	2-8°C	12Months	50pc/pkg
	ML6-115AS	<i>Bacillus subtilis</i> ATCC35021	$1 \times 10^6 \sim 5 \times 10^6$	2-8°C	12Months	50pc/pkg
	ML6-121AS	<i>G. steaotherophilus</i> ATCC7953	$1 \times 10^6 \sim 5 \times 10^6$	2-8°C	12Months	50pc/pkg
Capsule vial	ML6-115T	<i>Bacillus subtilis</i> ATCC35021	$1 \times 10^6 \sim 5 \times 10^6$	2-8°C	12Months	50pc/pkg
	ML6-121T	<i>G. steaotherophilus</i> ATCC7953	$1 \times 10^6 \sim 5 \times 10^6$	2-8°C	12Months	50pc/pkg
	ML3-121T*	<i>G. steaotherophilus</i> ATCC7953	$1 \times 10^3 \sim 5 \times 10^3$	2-8°C	12Months	50pc/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.stearothermophilus</i> ATCC12980	1x10 <sup>4</sup> ~5x10 <sup>4</sup>	2-8°C	12Months	30pc/pkg
	HS6-600	<i>G.stearothermophilus</i> ATCC12980	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	30pc/pkg
	HS3-600*	<i>G.stearothermophilus</i> ATCC12980	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-8°C	12Months	30pc/pkg
Paper strip	HP4-600	<i>G.stearothermophilus</i> ATCC12980	1x10 <sup>4</sup> ~5x10 <sup>4</sup>	2-8°C	12Months	50pc/pkg
	HP6-600	<i>G.stearothermophilus</i> ATCC12980	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8°C	12Months	50pc/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. stearothermophilus</i> ATCC7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25°C	12Months	50pc/pkg

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

# Biological Indicators

## 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	$1 \times 10^6 \sim 5 \times 10^7$	2-25°C	12Months	50pc/pkg
	ES3-600*	<i>Bacillus atrophaeus</i> ATCC9372	$1 \times 10^3 \sim 5 \times 10^3$	2-25°C	12Months	50pc/pkg
Paper strip	EP6-600*	<i>Bacillus atrophaeus</i> ATCC9372	$1 \times 10^6 \sim 5 \times 10^7$	2-25°C	12Months	50pc/pkg
	EP7-600*	<i>Bacillus atrophaeus</i> ATCC9372	$1 \times 10^7 \sim 5 \times 10^7$	2-25°C	12Months	50pc/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
Paper strip	GP2-9372*	<i>Bacillus atrophaeus</i> ATCC9372	$1 \times 10^2 \sim 5 \times 10^2$	2-8°C	12Months	50pc/pkg
	GP3-9372*	<i>Bacillus atrophaeus</i> ATCC9372	$1 \times 10^3 \sim 5 \times 10^3$	2-8°C	12Months	50pc/pkg
	GP4-9372*	<i>Bacillus atrophaeus</i> ATCC9372	$1 \times 10^4 \sim 5 \times 10^4$	2-8°C	12Months	50pc/pkg
	GP6-9372*	<i>Bacillus atrophaeus</i> ATCC9372	$1 \times 10^6 \sim 5 \times 10^6$	2-8°C	12Months	50pc/pkg
	GP3-8032	<i>Staphylococcus albus</i> 8032	$1 \times 10^3 \sim 5 \times 10^3$	≤-18°C	3Months	50pc/pkg
	GP3-8032*	<i>Staphylococcus albus</i> 8032	$1 \times 10^6 \sim 5 \times 10^6$	≤-18°C	3Months	50pc/pkg

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

# Bis/Culture Medium/Spore Suspensions

## 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	$1 \times 10^6 \sim 5 \times 10^6$	2-25°C	12Months	50pc/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	50pc/pkg
<i>Bacillus atrophaeus</i> medium	MTSB-2.5	EP6-600、DP6-160、GP3-9372、GP6-9372	2-8°C	12Months	50pc/pkg
Tryptic soy broth liquid medium	TSB-2.5	GP3-8032、SP6-115	2-8°C	12Months	50pc/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

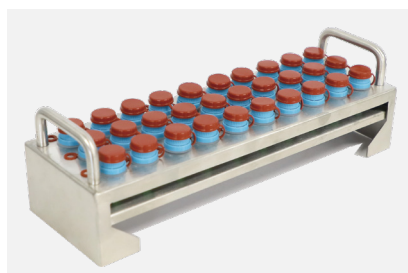
Note: Spore concentration of spore suspensions  $\geq 10^8$ cfu/ml

# Biological Indicators

## 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	Indicator → 
Turns Black	Indicator → 
•Indicator changes from yellow to black after sterilization	
Vapor Hydrogen Peroxide Chemical Indicator 	
Initial Green	Indicator → 
Turns Yellow	Indicator → 
•Indicator changes from green to yellow after sterilization	
Ethylene Oxide Sterilization Chemical Indicator 	
Initial Red	Indicator → 
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	200pc/pkg
CIs for autoclave steam	Used for chemical monitoring of sterilization effect in pressure steam sterilizer, etc.	2-25°C	12Months	200pc/pkg
CIs for Ethylene Oxide	Used for chemical monitoring of sterilization effect in EO sterilization cabinet, etc.	2-25°C	12Months	200pc/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