



# STERILIZATION VALIDATION SOLUTIONS FOR BIOLOGICAL AND CHEMICAL INDIKATORS

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# Biological Indicators

## 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	Article No.	Species	Population	Storage	Shelf Life	Packing
Self-contained	SS6-105	<i>Bacillus subtilis</i> ATCC 6633	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25 °C	12 months	50pcs/pkg
	SS6-115	<i>Bacillus subtilis</i> ATCC 35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25 °C	12 months	50pcs/pkg
	SS6-121	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25 °C	12 months	50pcs/pkg
Paper strip	SP6-115	<i>Bacillus subtilis</i> ATCC 35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25 °C	12 months	50pcs/pkg
	SP6-121	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25 °C	12 months	50pcs/pkg
	SP3-121*	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>5</sup> ~5x10 <sup>5</sup>	2-25 °C	12 months	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	Article No.	Species	Population	Storage	Shelf Life	Packing
Ampoule	ML6-115A	<i>Bacillus subtilis</i> ATCC 35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	50pcs/pkg
	ML6-121A	<i>G. stearotherophilus</i> ATCC 7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	50pcs/pkg
	ML3-121A*	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>5</sup> ~5x10 <sup>5</sup>	2-8 °C	12 months	50pcs/pkg
	ML6-115AS	<i>Bacillus subtilis</i> ATCC 35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	50pcs/pkg
	ML6-121AS	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	50pcs/pkg
Capsule vial	ML6-115T	<i>Bacillus subtilis</i> ATCC 35021	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	50pcs/pkg
	ML6-121T	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	50pcs/pkg
	ML3-121T*	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>5</sup> ~5x10 <sup>5</sup>	2-8 °C	12 months	50pcs/pkg

## 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	Article No.	Species	Population	Storage	Shelf Life	Packing
Self-contained	HS4-600	<i>G. stearothermophilus</i> ATCC 12980	1x10 <sup>4</sup> ~5x10 <sup>4</sup>	2-8 °C	12 months	30pcs/pkg
	HS6-600	<i>G. stearothermophilus</i> ATCC 12980	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	30pcs/pkg
	HS3-600*	<i>G. stearothermophilus</i> ATCC 12980	1x10 <sup>3</sup> ~5x10 <sup>3</sup>	2-8 °C	12 months	30pcs/pkg
Stainless steel strip	HP4-600	<i>G. stearothermophilus</i> ATCC 12980	1x10 <sup>4</sup> ~5x10 <sup>4</sup>	2-8 °C	12 months	50pcs/pkg
	HP6-600	<i>G. stearothermophilus</i> ATCC 12980	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-8 °C	12 months	50pcs/pkg

## 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	Article No.	Species	Population	Storage	Shelf Life	Packing
Self-contained	PS6-023	<i>G. stearothermophilus</i> ATCC 7953	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25 °C	12 months	50pcs/pkg

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

## Ampoule Opener

Type	Article No.	Material	Diameter / Dimensions
Grinding Wheel Ampoule Opener	8710075800001	Wheel material: silicon carbide	2 cm
Grinding Wheel Ampoule Opener, stainless steel (with metal cutting discs)	6490021960000	Removable, non-slip base	130 x 200 mm

## 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	Article No.	Species	Population	Storage	Shelf Life	Packing
Ampoule	DP6-160	<i>Bacillus atrophaeus</i> ATCC 9372	1x10 <sup>6</sup> ~5x10 <sup>6</sup>	2-25 °C	12 months	50pcs/pkg

## Culture Medium

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



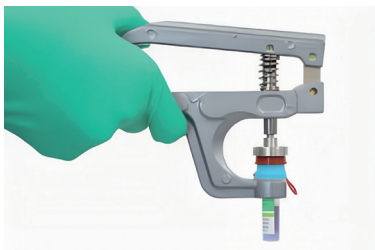
## Spore Suspensions

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

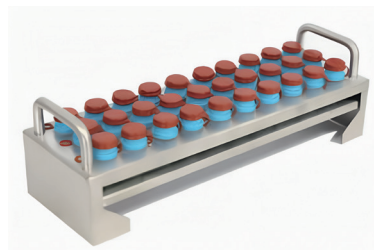


Note: Spore concentration of spore suspensions  $\geq 10^8$ cfu/ml

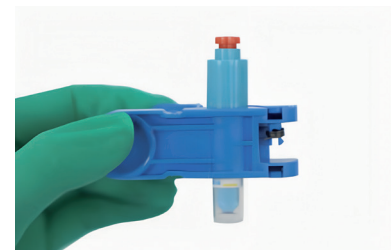
## Accessories of BIs



Hand pressure plier of self-contained BIs for hydrogen peroxide



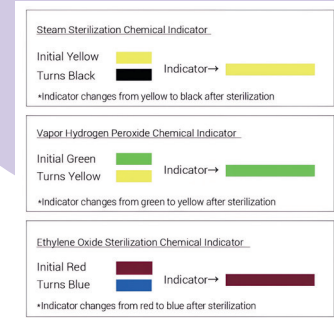
Test tube stand of self-contained BIs for hydrogen peroxide



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.



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	12 months	200pcs/pkg
CIs for Autoclave Steam	Used for chemical monitoring of sterilization effect in pressure steam sterilizer, etc.	2-25 °C	12 months	200pcs/pkg
CIs for Ethylene Oxide	Used for chemical monitoring of sterilization effect in EO sterilization cabinet, etc	2-25 °C	12 months	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	Article No.	Storage	Shelf Life	Packing
B-D Test Pack	KC2159	Temp 2-25 °C, RH < 50%	12 months	20 pcs/pkg
B-D Early Warning Test Pack	KC2159-5	Temp 2-25 °C, RH < 50%	12 months	20 pcs/pkg

# Evaluation Resister

## Biological Indicator

### 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 btest 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: ≤0.1kPa/min
Sterilization Target: Biological Indicator	Vacuum: 2 kPa	Non-condensableGas: ≤2.5%
Sterilization Chamber Volume: 5L	Time to Vacuum: <30 s	Superheated Steam: ≤5 °C
Dimensions: 175.0 x 78.0 x 95.0cm	Come-up Period: ≤8 s	Steam Quality: ≥0.98
Power Supply: AC 380V/50Hz	Sterilization TemperatureDeviation: ±0.4 °C	Sterilization Curve: Yes
Weight: 150 kg	Come-downPeriod: ≤5 s	Test Report: Yes
Electric HeatingPower: 9KW	Time Accuracy: ±1 s	Three-level Management: Yes

# Evaluation Resister

## Biological Indicator

### 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 $\pm 0.3\text{mg/L}$	Power Supply: 380VAC/50HZ
Hydrogen Peroxide Concentration Range 1~10mg/L	Time to Vacuum: $\leq 60\text{s}$	Power: 5KW
Hydrogen Peroxide Concentration Accuracy $\pm 0.3\text{mg/L}$	Leakage Rate: $\leq 0.13\text{kPa/min}$	Dimensions: 112 x 105 x 183 (cm)
Water Vapor Concentration Monitoring TD-LAS laser sensor	Single SterilizationQuantity: 20pcs	Weight: 700 kg
Water Content Probe 1~20mg/L	MaximumSingle Test Quantity: 24 self-contained BIs/ 24 carrier-type (sheet) BIs	
Compatible Indicator Types: compatible with both self-contained andcarrier (sheet) biological indicator tests		
Management Authority: three levels of management authority with GMP management requirements		

# Evaluation Resister

## Biological Indicator

### 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: $\leq 10s$	Power Supply: 380VAC/50HZ
Sterilizer Concentration: 100~1200mg/L	Time to Vacuum: $\leq 60s$	Power: 5KW
Sterilization Temperature: 29~65 °C	Leakage Rate: $\leq 0.13kPa/min$	Dimensions: 112 x 183 x 105 (cm)
RH: 30%~80%	Single Sterilization Quantity: 20pcs	Weight: 700 kg
Pressure Range: 4~20kPa	Electronic Signature: Yes	Test Report: Yes
Concentration Rising Period: $\leq 10s$	Sterilization Curve: Yes	

Management Authority: three levels of management authority with GMP management requirements

