

## Steel Spore Disc Biological Indicators Vaporized Hydrogen Peroxide (VH<sub>2</sub>O<sub>2</sub>)

*Geobacillus stearothermophilus* - Cell Line 7953 Monitoring

An inoculated carrier, 6 mm steel disc, of *Geobacillus stearothermophilus* (Cell Line 7953) with a population level of 10<sup>3</sup>, 10<sup>4</sup>, 10<sup>5</sup> or 10<sup>6</sup>. These Biological Indicators (BIs) for use in monitoring Vaporized Hydrogen Peroxide (VH<sub>2</sub>O<sub>2</sub>) sterilization processes. The BIs are designed for monitoring processes whether placed directly into the chamber, positioned in areas of a device which are the most difficult to sterilize or distributed throughout rooms and isolators. Steel Spore Discs are 6 mm in diameter and are available packaged in easy-to-access Tyvek®/ Tyvek® pouches (Please inquire for bulk & other packaging)



### Standard Features

- Convenient shelf packages of 100 units per box
- Products are accompanied by a Certificate of Analysis and are certified with population, purity, and resistance characteristics (D value, survival and kill where applicable)
- ISO 11138-1 Compliant

### Intended Use

The Spore Discs are utilized to monitor VH<sub>2</sub>O<sub>2</sub> sterilization process efficacy. The Spore Discs are labeled For Industrial Use Only.

### Instructions for Use

Place Spore Discs (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized. Package or wrap product as usual, if applicable.

Locate the test packages or Spore Discs in areas most difficult to sterilize, as outlined in your specific sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top) or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove Spore Discs or product from sterilizer.

Aseptically transfer the Spore Discs to Soybean Casein Digest Broth (SCDB).

Transfer one Spore Disc which has not been exposed in a sterilization process as a Positive Control.

**Incubation:** At least one unused tube of culture medium from the same lot should be incubated with the test series as a Negative Control. Place the cultured Spore Discs, the Positive Control and the Negative Control in an incubator set at 55°C to 65°C.

Incubate for a minimum of seven days or per a validated reduced incubation period.

**Monitoring:** Examine the Spore Discs daily during incubation. Record observations.

### Interpretation

Tubes which demonstrate turbidity with cream colored sediment are considered positive for growth of *Geobacillus stearothermophilus*. Tubes which remain clear and without sediment are considered negative for growth.

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are characteristic of the indicator organism.

**Positive Control:** Tube(s) should demonstrate turbidity with an orange-colored pellicle. If the Positive Control does not result in growth, the exposure is considered invalid. Check the conditions during incubation and verify the capability of the medium to support growth.

**Negative Control:** Tubes of media should remain clear. If the Negative Control results in growth, there is a potential for false positives.

## Technical Data

Physical Properties			
Process	VH <sub>2</sub> O <sub>2</sub>		
Disc Diameter	6 mm		
Pouch Dimensions	29 mm x 75 mm		
Packaging	100/Box		
Performance Characteristics			
Population	1.0 to 5.0 x 10 <sup>x</sup> per disc, where x = the population level of the Spore Disc		
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.		
VH <sub>2</sub> O <sub>2</sub> Resistance	D value at 55°C ± 5°C, 2.3 mg/L 1.0 to 3.0 minutes		
Post-Market Criteria	Population: 50% to 300% of certified population D value: ± 20% of the certified D value		
Monitoring Frequency			
For greatest control of sterilized goods, it is recommended that a minimum of ten (10) Spore Discs be included with every load.			
Compliance			
ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements USP <55> Biological Indicators – Resistance Performance Tests			
Disposal			
Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.			
Storage and Shelf Life			
Temperature	15°C to 30°C	Sunlight	Keep away from sunlight
Relative Humidity	20% to 70%	Moisture	Keep dry
Shelf Life	19 Months from the date of manufacture	Radioactivity	Protect from heat and radioactive sources
Caution	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Discs. Do not use damaged Spore Discs. Do not use after the expiration date. The Spore Discs contain live cultures and should be handled.		

## Ordering Information

Part Number	Description	Quantity
3031304	<i>Geobacillus stearothermophilus</i> Cell Line 7953, Stainless Steel Discs each 6 mm in Diameter, Individually Packaged in Tyvek®/Tyvek® Pouches, 100 per box, 103 population level, ISO 11138 compliant where applicable	100
3031305	<i>Geobacillus stearothermophilus</i> Cell Line 7953, Stainless Steel Discs each 6 mm in Diameter, Individually Packaged in Tyvek®/Tyvek® Pouches, 100 per box, 104 population level, ISO 11138 compliant where applicable	100
3031306	<i>Geobacillus stearothermophilus</i> Cell Line 7953, Stainless Steel Discs each 6 mm in Diameter, Individually Packaged in Tyvek®/Tyvek® Pouches, 100 per box, 105 population level, ISO 11138 compliant where applicable	100
3031307	<i>Geobacillus stearothermophilus</i> Cell Line 7953, Stainless Steel Discs each 6 mm in Diameter, Individually Packaged in Tyvek®/Tyvek® Pouches, 100 per box, 106 population level, ISO 11138 compliant where applicable	100

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