



STEEL SPORE DISCS For Monitoring Vaporized Hydrogen Peroxide (VH₂O₂)

Crosstex Code: SDS-06

Product Description

Steel Spore Discs for monitoring VH₂O₂ processes consist of:

- An inoculated carrier, 6 mm steel disc, of *Geobacillus stearothermophilus* (Cell Line 7953) with a population level of 10⁶
- Primary packaging in a Tyvek®/Mylar® pouch

Intended Use

The Spore Discs are utilized to monitor VH₂O₂ 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 cream colored sediment. 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.

Physical Properties

Process	VH ₂ O ₂
Disc Diameter	6 mm
Pouch Dimensions	57 mm x 70 mm
Packaging	100/Box

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that a minimum of ten (10) Spore Discs be included with every load.

Performance Characteristics

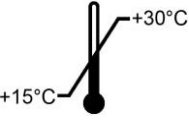

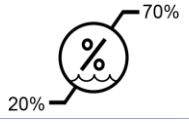



Population	1.0 to 5.0 x 10 ⁶ per disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
VH ₂ O ₂ Resistance	<i>D</i> value at 55°C ± 5°C, 2.3 mg/L 1.0 to 3.0 minutes
Post-Market Criteria	Population: 50% to 300% of certified population <i>D</i> value: ± 20% of the certified <i>D</i> value

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

USP <55> Biological Indicators – Resistance Performance Tests

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 70% Relative Humidity		Keep dry
<p>Shelf Life</p>	19 Months from the date of manufacture		Protect from heat and radioactive sources
	<p>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 with care.</p>		

Disposal

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

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