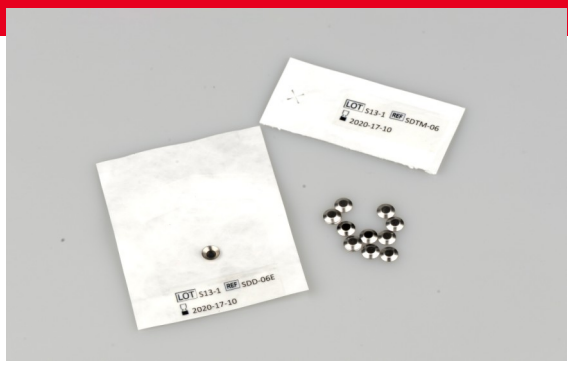
Technical Data Sheet



STEEL SPORE DISCS
For Monitoring Vaporized Hydrogen Peroxide (VH_2O_2) Processes

True Indicating Codes: SDTM-06 and SDTT-06

Product Description

Steel Spore Discs for monitoring VH_2O_2 processes consist of:

- An inoculated carrier, 6mm steel disc of *Geobacillus stearothermophilus* Cell Line 7953
- Primary packaging either in Tyvek®/Mylar® pouches (SDTM-06) or Tyvek® pouches (SDTT-06)

Indications for Use

The Spore discs are designed to monitor VH_2O_2 sterilization process efficacy. The Spore Discs are labeled for laboratory/industrial use only.

Physical Properties

Process	VH_2O_2
Disc Dimensions	6 mm
Pouch Dimensions	SDTM-06: 57 mm x 70 mm SDTT-06: 28.5 mm x 63.5 mm
Packaging	100 / Pack

Monitoring Frequency

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

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 one Spore disc to 5-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, True Indicating Code PGM-100, may be utilized in place of the SCDB.

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

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

Sterilization Process	Media Type	Minimum Incubation Time
VH_2O_2	SCDB	7 Days
	PGM-100	24 Hours

Monitoring: Examine the Spore Discs daily, whenever possible during incubation. Record observations.

Interpretation:

Where SCDB (standard or unmodified) was utilized: 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.

Where modified media, True Indicating Code PGM-100, was utilized: Tubes which transition in color from Purple to Yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain Purple in color and do not demonstrate turbidity are considered negative for growth.

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

Positive Control: Tube(s) should demonstrate turbidity and cream-colored sediment or demonstrate a color transition from Purple to Yellow where modified media has been utilized. 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 and Purple in where modified medium was utilized. If the Negative Control results in growth, there is a potential for false positives.

Compliance

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

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin which outlines the recommended methodology.

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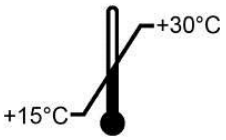
Performance Characteristics

Population	≥ 1.0 x 10^6 per Disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
VH_2O_2 Resistance	*D* value at 55°C ± 5°C, 2.3 mg/L ≥ 1.0 minutes
Post Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% relative humidity		Keep Dry
Shelf Life	18 months from the date of manufacture		Protect from heat and radioactive sources
	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.		

Disposal

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

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