



# Technical Data Sheet

## STEEL SPORE DISCS For Monitoring Vaporized Hydrogen Peroxide (VH<sub>2</sub>O<sub>2</sub>) Processes

True Indicating Code: SDAM-06 and SDAT-06

### Product Description

Biological indicator Steel Spore Discs for monitoring VH<sub>2</sub>O<sub>2</sub> processes consist of:

- An inoculated carrier, 6mm steel disc of *Bacillus atrophaeus* Cell Line 9372 with a population level of 10<sup>6</sup>
- Primary packaging in Tyvek®/Mylar® pouches (SDAM-06) or Tyvek® pouches (SDAT-06)

### Indications for Use

The Spore Discs are utilised to monitor VH<sub>2</sub>O<sub>2</sub> sterilization process efficacy. The Spore Discs are labeled for laboratory/industrial use only.

### Physical Properties

Process	VH <sub>2</sub> O <sub>2</sub>
Disc Dimensions	6 mm
Package Dimensions	SDAM-06: 57 mm x 70 mm SDAT-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 GGM-100 may be used 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 30°C to 40°C as outlined in the following table:

Sterilization Process	Media Type	Minimum Incubation Time
VH <sub>2</sub> O <sub>2</sub>	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 used: Tubes which demonstrate turbidity with cream/orange colored pellicle are considered positive for growth of *Bacillus atrophaeus*. Tubes which remain clear and without pellicle are considered negative for growth.

Where modified media, True Indicating code GGM-100 was used: Tubes which transition in color from Green to Yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain Green 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 should demonstrate turbidity with a cream/orange colored pellicle or demonstrate a color transition from Green 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: Tube of media should remain clear and Green in color 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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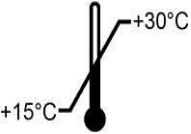

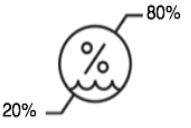





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## Performance Characteristics

Population	$\geq 1.0 \times 10^6$ per Disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
VH2O2 Resistance	<i>D</i> value at $55^\circ\text{C} \pm 5^\circ\text{C}$ , 2.3 mg/L $\geq 1.0$ minutes
Post Market Criteria	Population: 50% to 300% of certified population <i>D</i> value: $\pm 20\%$ of the certified <i>D</i> 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.

