

Certificate of Analysis

This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1 and ISO 11138-3.

Product Name: Spore Threads Organism: Geobacillus stearothermophilus

LOT S76-2 **REF** TTB-06

☐ 2020-10-25 (YYYY-MM-DD)

2018-10-25 For use in Monitoring: Steam

Derived from: Cell Line 7953 Quantity 100 threads Population: 2.0 x 10⁶ per 30 mm thread

Resistance Characteristics

Survival Kill

Steam (121°C): 1.7 minutes 7.4 minutes 17.5 minutes

z value

Based on determinations at 118°C, 121°and 130°C: 9.5 °C

The *D* value(s) were determined per the fraction negative method and are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results, therefore, should determine the suitability for their particular use.

Recovery

After exposure to the sterilization process, aseptically transfer each carrier to an individual tube containing 5-15 mL of Soybean Casein Digest Broth (SCDB). Incubate at 55° - 65°C for a minimum of 7 days or per validated reduced incubation time.

Examine tubes for growth, daily or as frequently as possible. Tubes showing typical growth of *Geobacillus stearothermophilus* will display a cream-colored sediment.

Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the biological indicator.

Storage and Shelf Life

+15°C-	Room Temperature (15°- 30°C)	*	Keep away from sunlight.
80%	20% to 80% Relative Humidity	**	Protect from heat, radioactive sources, and sterilizing agents.
Shelf Life	24 Months from the date of manufacture		

Disposal: Autoclave, steam at 121°C for not less than 30 minutes, or incinerate (standard microbial waste; non-pathogenic species).

Quality Approval Date