



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

Product Name: Spore Discs

For use in Monitoring: Steam Processes

Organism: *Geobacillus stearothermophilus*

Derived from: ATCC® 7953

LOT S75-1

REF DT-06

Quantity: 100 discs

2018-10-25

2020-10-25 (YYYY-MM-DD)

Performance Characteristics		
Population: 2.0 x 10 ⁶ per 6 mm disc		
D value	Survival	Kill
Steam (121°C): 1.7 minutes	7.4 minutes	17.5 minutes
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. Survival-Kill times calculated using USP and ISO survival time and kill time formulae.		
z value: 9.5°C Based on D value determinations at 118°C, 121°C and 130°C.		

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 to +30°C	Room Temperature (15° - 30°C)		Keep away from sunlight
20% to 80%	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	30 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 ASSURANCE APPROVAL

August 24, 2022
DATE