



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

Product Name: Spore Strips

For use in Monitoring: Steam Formaldehyde Processes

Organism: *Geobacillus stearothermophilus*

Derived from: ATCC®7953

LOT S700-1

REF STF-06

Quantity 100 Strips

2022-01-01

2024-07-01 (YYYY-MM-DD)

Performance Characteristics		
Population: 1.0 x 10 ⁶ per 6 mm x 30 mm strip		
D value	Survival	Kill
Steam Formaldehyde (1 mol/60°C): 4.0 minutes	18.5 minutes	42.4 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.		

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			
	Room Temperature (15° - 30°C)		Keep away from sunlight
	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	30 Months from the date of manufacture The stability of this product configuration is based on evaluation of moist heat resistance.		

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

QUALITY ASSURANCE APPROVAL

October 19, 2022
DATE