

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 Strips

For use in Monitoring: Steam Processes

Organism: Geobacillus stearothermophilus

Derived from: ATCC® 7953

LOT

S700-0

REF ST-06

Quantity:

100 strips

<u>~</u> 2021-01-01

2023-07-01 (YYYY-MM-DD)

Performance Characteristics				
Population: 2.0 x 10 ⁶ per 6 mm x 30 mm strip				
D value	Survival	Kill		
Steam (121°C): 1.5 minutes	6.5 minutes	15.4 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.

z value: 10.0°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	Room Temperature (15° - 30°C)	类	Keep away from sunlight	
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).

August 24, 2022

QUALITY ASSURANCE APPROVAL

DATE