



BIOLOGICAL INDICATOR – SPORE AMPULE

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

Product Name: Spore Ampule + Negative Controls

Organism: *Geobacillus stearothermophilus*

LOT S79-2

REF ATM-06

Volume 0.4 mL

 2018-10-25

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

For use in Monitoring: Steam

Derived from: ATCC® 7953

Population: 2.0×10^6 per ampule

Resistance Characteristics

D value
Steam (121°C): 17. minutes

Survival
7.4 minutes

Kill
17.5 minutes

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

The *D* value was 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 are calculated based on the formulae outlined in USP and ISO 11138-1.

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

Storage and Shelf Life

	Refrigerate (2 - 8°C)		Keep away from sunlight.
	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

FOR LAB/INDUSTRIAL USE ONLY.

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