



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

Product Name: Self-Contained Biological Indicator (SCBI)

For use in Monitoring: Steam

Organism: *Geobacillus stearothermophilus*

Derived from: ATCC® 7953

LOT S758-0

REF SCST-05

Quantity: 50 SCBIs

2020-10-20

2022-10-20

Performance Characteristics		
Population:	1.6x 10 ⁵ per 6 mm disc	
D value	Survival	Kill
Steam 121°C: 1.7 minutes	5.5 minutes	15.6 minutes
Steam 132°C: 0.1 minutes	0.4 minutes	0.9 minutes
Steam 135°C: 0.02 minutes	0.07 minutes	0.18 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.		
z value: 7.8°C Based on D value determinations at 118°C, 121°C and 130°C		

Recovery

After exposure to the sterilization process, activate the SCBI by depressing the cap of the unit applying sufficient pressure to break the media ampule. Ensure the Spore Disc is immersed in the growth medium. Incubate at 55°-65°C for a minimum of 10 hours. Incubate an unexposed SCBI which has been activated as a Positive Control.

Examine SCBIs for growth as frequently as possible. SCBIs which are positive for growth of *Geobacillus stearothermophilus* will transition from Purple to Yellow and/or display a cream-colored sediment. If the Positive Control does not yield a Yellow color and/or turbidity, the test is not valid and the incubation conditions should be verified.

Remove SCBIs which are positive for growth (Yellow and/or turbid) from incubation promptly. Continued incubation of the SCBIs will cause the growth medium to evaporate and lead to the color of positive units to revert from Yellow back to a dark Purple color.

SCBIs which are negative for growth will remain clear and Purple in color. Negative SCBIs (Clear and Purple after incubation) indicate the cycle/process was effective.

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	Labeled with the shorter expiration date of the two components with individual expiry periods: the media ampule and the Spore Disc.		

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

Quality Approval _____

Date _____