



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

Product Name: Self-Contained Biological Indicator (SCBI)

For use in Monitoring: Formaldehyde

Organism: *Geobacillus stearothermophilus*

Derived from: ATCC® 7953

LOT S700-1

REF MSCFT-06

2022-01-01

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

Quantity: 100 SCBIs

Performance Characteristics

Population: 2.0 x 10⁶ per 6 mm Disc

Recovery:

After exposure to the sterilization process, activate the SCBI by pressing on the sides 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 24 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 from 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. 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 Approval

October 19, 2022
Date