



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)

Organism: *Geobacillus stearothermophilus*

**LOT** S71-8

**REF** SCST-06

2020-03-18 (YYYY-MM-DD)

2018-03-18

For use in Monitoring: Steam

Derived from: Cell Line 7953

Quantity 50 SCBIs

Population:  $2.0 \times 10^6$  per 6 mm disc

#### Resistance Characteristics

Steam (121°C): 1.5 minutes

Survival  
6.5 minutes

Kill  
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.

#### Recovery

After exposure to the sterilization process, activate the SCBI by depressing the cap until an audible click is heard and the media ampule breaks. 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.

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

+15°C to +30°C	Room Temperature (15° - 30°C)		Keep away from sunlight
20% to 80%	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