



This lot of product meets the accepted performance criteria recommended in USP, ISO 11138-1 and ISO 11138-2.

Product Name: Self-Contained Biological Indicators (SCBIs)

For use in Monitoring: Ethylene Oxide (EO)

Organism: *Bacillus atrophaeus*

Derived from: ATCC® 9372

LOT A24-0

REF SCEA-06

Quantity: 50 SCBIs

2019-05-17

2021-05-17 (YYYY-MM-DD)

Performance Characteristics		
Population: 2.6x 10 ⁶ per 6 mm disc		
D value	Survival	Kill
EO (100%, 600 mg/L, 54°C, 60% RH): 2.2 minutes	9.8 minutes	22.9 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 pressing 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 30°-40°C for a minimum of 48 hours. Incubate an unexposed activated SCBI as a Positive Control.

Examine SCBIs for growth. SCBIs which are positive for growth of *Bacillus atrophaeus* will transition from Green to Yellow and/or display a pellicle at the top of the media which is cream to orange in color. 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 darker Blue-Green color.

SCBIs which are negative for growth will remain clear and Green in color. Negative SCBIs (clear and Green 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	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 _____