



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)

Organism: *Bacillus atrophaeus*

LOT A1-9

REF SCEA-06

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

2018-03-18

For use in Monitoring: Ethylene Oxide and Dry Heat

Derived from: Cell Line 9372

Quantity 50 SCBIs

Population: 2.0×10^6 per 6 mm disc

Resistance Characteristics

Ethylene Oxide D value (600 mg/L, 54°C, 60% RH): 2.5 minutes

Survival
10.8 minutes

Kill
25.7 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 of the unit until an audible click is heard and the media ampule breaks. 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.

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