TRUE INDICATING PRODUCTS

Certificate of Analysis

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 A1-12 REF MSCEA-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 100 SCBIs Population: 2.0×10^6 per 6 mm disc

Resistance Characteristics

		Survival	Kill
Ethylene Oxide D value (600 mg/L, 54˚C, 60% RH):	2.5 minutes	10.8 minutes	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 pressing 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 30˚ - 40˚C for a minimum of 48 hours. Incubate an unexposed activated SCBI as a Positive Control.

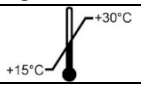
Examine SCBIs for growth. SCBIs which are positive for growth of *Bacillus atrophaeus* will transition from Green to Yellow and/or display a pellicle at the top of the media which is cream to orange in color. If the Positive Control does not yield a Yellow color and/or turbidity, the test is not valid 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

	Room Temperature (15˚- 30˚C)		Keep away from sunlight
	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

Manufactured by: True Indicating LLC 946 Kane St, Suite A Toledo, Ohio 43612 www.trueindicating.com
T: 419-476-7119 E: info@trueindicating.com