

MINI SELF CONTAINED BIOLOGICAL INDICATORS (MSCBIs) For Monitoring Ethylene Oxide (EO) Processes

True Indicating Code: MSCEA-06

DOMINIQUE DUTSCHER SAS

Product Description

Mini Self-Contained Biological Indicators (MSCBIs) for monitoring (EO) processes consist of:

- A polypropylene vial and cap
- A crushable media ampule which contains modified Tryptic Soy Broth (TSB) with a pH indicator. The modified TSB will transition from the initial Blue-Green color to Yellow and/or demonstrate turbidity in the presence of bacterial growth.
- An inoculated carrier (disc) of *Bacillus atrophaeus* Cell Line 9372 with a population level of 10^6.

Indications for Use

The MSCBIs may be utilized to monitor EO sterilization efficacy through equipment and process validation and routine monitoring. The MSCBIs are labeled for laboratory/industrial use only.

Physical Properties

Process	EO
Dimensions	8.3 mm x 46 mm
Packaging	100 per box
Chemical Indicator	Each MSCBI contains a CI strip on the vial label. The CI should transition from Violet to Green when exposed to a EO process.

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more MSCBIs be included with every load.

Instructions for Use

Exposure: MSCBIs may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or MSCBIs in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove MSCBIs or product from sterilizer

MSCBIs may be held at room temperature for up to 72 hours post-exposure prior to activation without any impact to the performance. If the processed MSCBIs are not activated within 72 hours of exposure, the cycle should be repeated.

946 Kane St. Suite A, Toledo, OH, 43612
United States
@: info@trueindicating.com
www.trueindicating.com

Activation: Squeeze the sides of the unit until an audible click is heard and the glass media ampule contained within is crushed. Once the media ampule is activated the SCBI must remain in an upright position to avoid leaking and premature evaporation of media. Ensure that the disc is immersed in the growth medium. Activate one MSCBI which has not been exposed in a sterilization process as a Positive Control.

Incubation: Place the processed, activated MSCBI and the Positive Control in a vertical position in an incubator at 30° C to 40°C for a minimum of 48 hours. If incubation is required for greater than 72 hours, the MSCBI should be capped or sealed to avoid evaporation of the media.

Monitoring: Examine the MSCBIs and record observations.

All positive MSCBIs should be disposed of immediately. Do not continue to incubate a positive MSCBI.

Interpretation: Control MSCBI: The Positive Control MSCBI should exhibit a color change to Yellow and/or demonstrate turbidity. If the Positive Control as does not show signs of growth, consider the test invalid.

Test MSCBI: A passing sterilization cycle is indicated by no signs of turbidity and the Blue-Green color remains and does not transition to Yellow. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow.

Chemical Indicator (CI): The CI strip (along the top of the MSCBI label) should transition from Violet to Green when exposed to an EO process. Lack of color change or a partial change in color of the CI does not necessarily indicate failure. The CI does not prove efficacy of sterilization; the biological result should be used to gauge efficacy of the sterilization cycle.

For unexpected positives, it is recommended that a Gram Stain be performed. Gram positive rods are indicative for

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1:General requirements

ISO 11138-2 sterilization of healthcare products – Biological indicators – Part 2 Biological indicator for ethylene oxide sterilization processes.

USP <55> Biological Indicators – Resistance Performance Tests

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin which outlines the methodology.

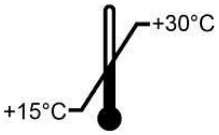
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Performance Characteristics

Population	≥1.0 x 10^6 per Disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
EO Resistance	*D* value at 54°C ± 1°C, 600 ± 30mg/L, 60 ± 10% RH ≥2.0 minutes The EO *D* value range is based on the requirements outlined in the USP, ISO 11138-2. The EO *D* value is determined using 100% Ethylene Oxide (EO). Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1
Post-Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value Survival Time: All MSCBIs result in growth at the certified survival time Kill Time: All MSCBIs result in no growth at the certified kill time

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep dry
	Do not freeze		Protect from heat, radioactive sources & sterilizing agents
Shelf Life	The shelf life of the MSCBI is based on the shorter of two individual components (the media ampule and inoculated carrier), which have independent expiration periods. This is usually 36 months from the date of manufacture.		
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the MSCBIs. Do not use damaged MSCBIs or MSCBIs which demonstrate turbidity or have transitioned to a Yellow color. Do not use after expiration date. Do not refrigerate. The MSCBIs contain live cultures and should be handled with care.		

Disposal

Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

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