

**Mini Self-Contained Biological Indicator (MSCBI):
Steam**

Physical Properties

Organism	<i>Geobacillus stearothermophilus</i> cell line 7953
Description	Vial containing a spore disc with specified population of spores and modified Soybean Casein Digest Broth (SCDB) with bromocresol purple pH indicator growth medium encased in a hermetically sealed glass ampoule. MSCBIs have known resistance to steam sterilization processes.
Dimensions	0.34" (0.86 cm) x 1.90" (4.83 cm)

Guidelines for Use

Application	Ideal for use in monitoring steam sterilization processes.
Shelf Life	Labeled with the shorter shelf life of the two components, the spore disc and growth medium ampoule, which have independent expiration periods.
Activation	Following exposure, remove MSCBIs from sterilizer and squeeze vial to crush media ampoule. Tap the unit on a hard surface in a vertical position to move the growth medium as necessary to ensure that the spore disc is bathed by the growth medium.
Incubation	Place activated MSCBIs into a 55-65°C incubator for a minimum of 24 hours. All positive MSCBIs should be recorded and disposed of immediately. Do not continue to incubate a positive MSCBI. Continued growth may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in a color reversion that is visibly darker than a sterile unit. These should be considered as positive for growth. Avoid misinterpretation by checking for growth daily and removing positives immediately.
Growth Indicator	The acid production associated with bacterial growth causes a shift in the pH and the color of the growth medium from purple to yellow.
Storage Conditions	Room temperature 15 – 30°C. Protect MSCBIs from exposure to sterilizing agents, direct sunlight and high temperatures. Do not refrigerate or freeze.
Clean Up/Disposal	Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

Performance Characteristics

Population	1.0 to 5.0 x 10 ⁵ spores per MSCBI Other population levels are available, please inquire for availability and lead time.
Steam D-value (121°C)	1.5 to 3.0 minutes
Results Availability	24 hours
Resistance	The certified d-value(s) are typically determined based on the MSCBI configuration. Placement of the MSCBI into a device or container will impact the resistance of spores based on the influence of the device/container on the penetration rate of the steam. The certified d-value(s) serve as a guide and are only reproducible when performed under the exact conditions (exposure parameters, culture and incubation conditions) the initial d-value was determined.
Compliance	FDA 510(k): K113302/ANSI/AAMI/ISO 11138-1:2006.

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