



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

Product Name: Self-Contained Biological Indicator (SCB) For use in Monitoring: Hydrogen Peroxide/Plasma

Organism: *Geobacillus stearothermophilus*

Derived from: ATCC® 7953

LOT S759-0

REF MSCPT-06

Quantity 100 SCBIs

2020-11-18

2022-11-18 (YYYY-MM-DD)

| Performance Characteristics | | |
|---|-------------|--------------|
| Population: 1.3 x 10 ⁶ per 6 mm disc | | |
| D value | Survival | Kill |
| Hydrogen Peroxide/Plasma (2.3 mg/L, at 50°C): 1.6 minutes | 6.6 minutes | 16.1 minutes |
| The D value was 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 on 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 55°-65°C for 24 to 72 hours. Incubation beyond 72 hours may result in evaporation of the growth medium.

Incubate an unexposed SCBI which has been activated as a Positive Control.

Examine SCBIs for growth as frequently as possible. SCBIs which are positive for growth of *Geobacillus stearothermophilus* will transition from Purple to Yellow and/or display a cream-colored sediment. 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 dark Purple color.

SCBIs which are negative for growth will remain clear and Purple in color. Negative SCBIs (Clear and Purple 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 | Labeled with the shorter expiration date of the two components with individual expiry periods: the media ampule and the Spore Disc. | | |

Disposal: Autoclave, steam at 121°C for not less than 30 minutes, or incinerate (standard microbial waste; non-pathogenic species).

Quality Approval

Date