



This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1 and ISO 11138-2.

Product Name: Spore Threads

For use in Monitoring: Ethylene Oxide

Organism: *Bacillus atrophaeus*

Derived from: ATCC® 9372

LOT A1-00

REF TA-06

Quantity: 100 Threads

2020-02-20

2022-02-20 (YYYY-MM-DD)

| Performance Characteristics | | | |
|--|---------------------------------|-------------|--------------|
| Population: | 2.0x 10 ⁶ per Thread | | |
| <i>D</i> value | | Survival | Kill |
| Ethylene Oxide (600 mg/L, 54°C, 60% RH): | 2.0 minutes | 8.7 minutes | 20.6 minutes |
| The <i>D</i> 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, aseptically transfer each carrier to an individual tube containing 5-15 mL of Soybean Casein Digest Broth (SCDB). Incubate at 30° - 40°C for a minimum of 7 days or per validated reduced incubation time.

Examine tubes for growth, daily or as frequently as possible. Tubes showing typical growth of *Bacillus atrophaeus* will display a pellicle at the top of the media which is cream to orange in color.

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 ASSURANCE APPROVAL

DATE