



This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1, ISO 11138-2 and ISO 11138-4.

Product Name: Spore Discs

Organism: *Bacillus atrophaeus*

LOT A3-10

REF DA-06

2020-10-25 (YYYY-MM-DD)

2018-10-25

For use in Monitoring: Ethylene Oxide and Dry Heat

Derived from: Cell Line 9372

Quantity 100 discs

Population: 2.0×10^6 per 6 mm disc

Resistance Characteristics

		Survival	Kill
Ethylene Oxide D value (600 mg/L, 54°C, 60% RH):	2.0 minutes	8.7 minutes	20.6 minutes
Dry Heat D value (160°C):	2.0 minutes	8.7 minutes	20.6 minutes

z value

Based on determinations at 150°C, 160°and 180°C: 31.0 °C

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, 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 Approval

Date