



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

Product Name: Spore Discs

For use in Monitoring: Ethylene Oxide

Organism: *Bacillus atrophaeus*

Derived from: ATCC® 9372

**LOT** A00-1

**REF** DA-06

Quantity: 100 discs

2020-01-01

2023-01-01 (YYYY-MM-DD)

Performance Characteristics		
Population: 2.0 x 10 <sup>6</sup> per 6 mm disc		
D value	Survival	Kill
Ethylene Oxide (600 mg/L, 54°C, 60% RH): 2.0 minutes	8.7 minutes	20.6 minutes
<p>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. Survival-Kill times calculated using USP and ISO survival time and kill time formulae.</p>		

### 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	36 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).

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QUALITY ASSURANCE APPROVAL

February 27, 2023  
DATE