



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

Product Name: Biological Indicator For use in Monitoring: Vaporized Hydrogen Peroxide (VH₂O₂)

Organism: *Geobacillus stearothermophilus* Derived from: Cell Line 7953

LOT S71-0 **REF** WTH-06 Quantity: 100 Wires
 2020-02-20 2021-08-20 (YYYY-MM-DD)

Performance Characteristics		
Population:	2.0 x 10 ⁶ per Wire	
D value	Hydrogen Peroxide 50°C ± 5°C, 2.3 ± 0.4 mg/L	2.0 minutes
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 55°-65°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 *Geobacillus stearothermophilus* will display a cream-colored sediment.

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	18 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

January 29, 2021
DATE