

# INOCULATED CARRIER SPORE DISCS

## For Monitoring Ethylene Oxide (EO) & Dry Heat

Excelsior Code: DN-06E & DN18-06E



### Product Description

Biological indicator Spore Discs for monitoring EO and Dry Heat processes consist of:

- An inoculated carrier, 3mm or 6mm Disc of *Bacillus atrophaeus* (Cell Line 9372)
- Primary packaging in bulk

### Indications for Use

The Spore Discs are utilised to monitor EO and Dry Heat sterilisation process efficacy. The Spore Discs are labelled for industrial use only.

### Instructions for Use

Place Spore Discs (a minimum of 10 per exposure is recommended) inside representative materials to be sterilised or within the chamber directly. Package or wrap product as usual, if applicable.

Locate the test packages or Spore Discs in areas most difficult to sterilise, as outlined in your specific sterilisation validation protocol (usually four corners front, four corners rear, centre-centre and centre-top) or according to standard operating procedure. Run the cycle.

After sterilisation or exposure, remove Spore Discs or product from steriliser



Spore Discs may be held at room temperature up to 96 hours post-exposure prior to transfer without any impact to the performance. If the processed Spore Discs are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated

Aseptically transfer the Spore Disc from the primary packaging and transfer to 10-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Excelsior code GMBTB-100E may be used in place of the SCDB.

Transfer one Spore Disc which has not been exposed in a sterilisation process as a Positive Control.

**Incubation:** At least one unused tube of culture medium from the same lot should be incubated with the test series as a Negative Control. Place the cultured Spore Discs, the Positive Control and the Negative Control in an incubator set at 30°C to 40°C.

Spore Discs cultured in SCDB should be incubated for a minimum of 7 days or per a validated reduced incubation period.

Spore Discs cultured in modified growth medium SCDB Excelsior code GMBTB-100E should be incubated for a minimum of 48 hours.

**Monitoring:** Examine the Spore Discs daily during incubation. Record observations.

## Interpretation:

Where SCDB (standard or unmodified) was used:

Tubes which demonstrate turbidity with cream/orange coloured pellicle are considered positive for growth of *Bacillus atrophaeus*. Tubes which remain clear and without formation of pellicle are considered negative for growth.

Where modified media, Excelsior code GMBTB-100E was used:

Tubes which transition in colour from green to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain green in colour and do not demonstrate turbidity are considered negative for growth.

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are indicative for the indicator organism.

Positive Control: Tube should demonstrate turbidity with a cream/orange coloured pellicle or demonstrate a colour transition from green to yellow where modified media has been utilised. If the Positive Control does not result in growth, the exposure is considered invalid. Check the conditions during incubation and verify the capability of the medium to support growth.

Negative Control: Tube of media should remain clear and green in colour where modified medium was utilised. If the Negative Control results in growth, there is a potential for false positives

## Physical Properties

Process	EO and Dry Heat
Disc Dimensions	DN-06E: 6 mm DN18-06E: 3mm
Packaging	100 / pack

## Monitoring Frequency

For greatest control of sterilised goods it is recommended that a minimum of ten (10) Spore Discs be included with every load.

## Performance Characteristics

Population	$\geq 1.0 \times 10^6$ per Disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
EO Resistance	<p><math>D</math> value at <math>54^\circ\text{C} \pm 1^\circ\text{C}</math>, <math>600 \text{ mg/L} \pm 30 \text{ mg/L}</math>, <math>60\% \text{ RH} \pm 10\% \text{ RH}</math>  <math>\geq 2.0</math> minutes</p> <p>The EO <math>D</math> value range is based on the requirements outlined in the USP, ISO 11138-2. The EO <math>D</math> value is determined using 100% EO.</p> <p>Survival – Kill Times            Calculated based on the formulations outlined in the USP, ISO 11138-1</p>
Dry Heat Resistance	<p><math>D</math> value at <math>160^\circ\text{C} \pm 1^\circ\text{C}</math>  <math>\geq 2.0</math> minutes</p> <p>Survival – Kill Times            Calculated based on the formulations outlined in the USP, ISO 11138-1</p> <p>Z value:  <math>\geq 20^\circ\text{C}</math></p> <p>Determined based on three temperatures in the range of <math>150^\circ\text{C}</math> to <math>180^\circ\text{C}</math>. Excelsior typically uses <math>D</math> values determined at <math>150^\circ\text{C}</math>, <math>160^\circ\text{C}</math> and <math>180^\circ\text{C}</math> for z value calculation.</p>
Post Market Criteria	<p>Population: 50% to 300% of certified population</p> <p><math>D</math> value: <math>\pm 20\%</math> of the certified <math>D</math> value</p> <p>Survival Time: All Spore Discs result in growth at the certified survival time</p> <p>Kill Time: All Spore Discs result in no growth at the certified kill time</p>

## Compliance

ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1: General Requirements

ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

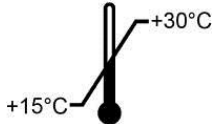





ISO 11138-4 Sterilization of health care products – Biological indicators – Part 4: Biological indicators for Dry Heat sterilization processes

USP <55> Biological Indicators – Resistance Performance Tests

Excelsior Scientific has a validated method for Total Viable Spore Count. Please inquire for the Technical data sheet entitled “Population Verification for Biological Indicator Mini Strips (2 mm x 10 mm), Discs (steel, paper and glass fibre), Threads, Wires and Coupons” to ensure consistent methodologies are being utilised when performing verification testing

USP Biological/Official Monographs

## Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% relative humidity		Keep Dry
Shelf Life	24 months from the date of manufacture		Protect from heat and radioactive sources
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Discs. Do not use damaged Spore Discs. Do not use after the expiration date. The Spore Discs contain live cultures and should be handled with care.		

## Disposal

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.