

# BIOLOGICAL INDICATOR MINI SPORE STRIPS

## For Monitoring Steam Sterilisation Processes

Excelsior Code: STS-062E & STS-062BE

### Product Description

Biological indicator Mini Spore Strips for monitoring steam processes consist of:

- An inoculated carrier, 2mm x 10mm strip of *Geobacillus stearothermophilus* (Cell Line 7953)
- Primary packaging in bulk (STS-062BE) or a glassine envelope (STS-062E)



### Indications for Use

The Mini Spore Strips are utilised to monitor Steam sterilisation process at 121°C to 137°C. The Mini Spore Strips are labelled for industrial use only.

### Instructions for Use

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

Locate the test packages or Mini Spore Strips 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 Strips or product from steriliser



Spore Strips 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 Strips are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated

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

Transfer one Mini Spore Strip 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 Mini Spore Strips, the Positive Control and the Negative Control in an incubator set at 55°C to 65°C.

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

Mini Spore Strips cultured in modified growth medium SCDB Excelsior code GMBCP-100E should be incubated for a minimum of 24 hours.

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

## Interpretation:

Where SCDB (standard or unmodified) was used:

Tubes which demonstrate turbidity with cream coloured sediment are considered positive for growth of *Geobacillus stearothermophilus*. Tubes which remain clear and without sediment are considered negative for growth.

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

Tubes which transition in colour from purple to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain purple 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 and cream coloured sediment or demonstrate a colour transition from purple 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 purple in colour where modified medium was utilised. If the Negative Control results in growth, there is a potential for false positives

## Physical Properties

Process	Steam
Strip Dimensions	2mm x 10 mm
Glassine Dimensions	Envelope (STS-062E): 30mm x 38mm
Packaging	100 / Pack

## Monitoring Frequency

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

## Performance Characteristics

Population	$\geq 1.0 \times 10^6$ per Strip
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	<p><i>D</i> value at <math>121^\circ\text{C} \pm 0.5^\circ\text{C}</math>  <math>\geq 1.5</math> minutes</p> <p>The Steam <i>D</i> value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food &amp; Drug Administration (FDA).</p> <p>Survival – Kill Times            Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA.</p> <p><i>z</i> value  <math>\geq 6^\circ\text{C}</math></p> <p>Determined based on three temperatures in the range of <math>110^\circ\text{C}</math> to <math>138^\circ\text{C}</math>. Excelsior Scientific typically utilises <i>D</i> values determined at <math>110^\circ\text{C}</math>, <math>121^\circ\text{C}</math> and <math>130^\circ\text{C}</math> for <i>z</i> value calculation.</p>
Post Market Criteria	<p>Population: 50% to 300% of certified population</p> <p><i>D</i> value: <math>\pm 20\%</math> of the certified <i>D</i> value</p> <p>Survival Time: All Spore Strips result in growth at the certified survival time</p> <p>Kill Time: All Spore Strips 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

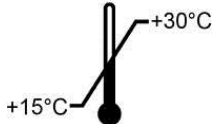





ISO 11138-3 Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

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 Strips” to ensure consistent methodologies 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 Strips. Do not use damaged Spore Strips. Do not use after the expiration date. The Spore Strips 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.