
GENERAL DESCRIPTION

The VERIFY Dual Species Self-Contained Biological Indicator (SCBI) is for use in monitoring common steam and ethylene oxide (EO) gas sterilization processes.

Each indicator is completely self-contained, combining a disc inoculated with dual spore species (*Geobacillus stearothermophilus* and *Bacillus atrophaeus*) and an ampule of specifically formulated soybean casein digest growth medium with a pH indicator. The VERIFY Dual Species SCBI is designed to be sealed after processing, reducing the risk of contamination (and consequent false positives) or growth medium evaporation.

Chemical indicators on each vial provide immediate proof of processing. Following incubation, a vivid color change from blue/purple to yellow and/or vial becoming turbid gives unmistakable evidence of microbial growth. If no microbial growth occurs, the vial remains blue and without turbidity.

STERIS has validated a reduced incubation time for the VERIFY Dual Species SCBI. A 24-hour incubation time has been validated for steam sterilization and a 48-hour incubation time has been validated for ethylene oxide (EO). Sufficient growth medium is provided for incubation up to seven days, if desired.

APPLICATION

The VERIFY Dual Species SCBIs are designed and validated for use in installation testing and routine monitoring of ethylene oxide sterilizers, and for installation testing and routine monitoring of steam sterilizers operating at:

- 250°F (121°C) 30-minute gravity steam sterilization cycles for packaged items
- 270°F (132°C) 3-minute gravity flash steam sterilization cycles for unpackaged items
- 270°F (132°C) 4-minute dynamic air removal steam sterilization cycles for packaged items
- 270°F (132°C) 4-minute EXPRESS abbreviated steam sterilization cycles for single-wrapped items
- 275°F (135°C) 3-minute dynamic air removal steam sterilization cycles for packaged items
- 275°F (135°C) 10-minute gravity steam sterilization cycles for packaged items
- 275°F (135°C) 3- or 10-minute gravity flash steam sterilization cycles for unpackaged items

FEATURES

BENEFITS

24-hour reduced incubation time for steam and 48-hour reduced incubation time for EO	Fast release of processed items
Dual species: <i>Geobacillus stearothermophilus</i> and <i>Bacillus atrophaeus</i>	Reduces inventory
Dual chemical indicators on label; one for steam and one for ethylene oxide	Provide immediate proof of processing with steam or EO
Vivid color change of pH indicator during incubation to indicate microbial growth	pH indicator makes positives easier to identify
Complete system is self-contained, including BI media and pH indicator	Reduces chances for false positives due to poor aseptic transfer technique

TECHNICAL PROPERTIES

Spore carrier type: filter paper

Spore carrier: 1/4" diameter (6.35 mm) disc

Species: *Geobacillus stearothermophilus* (strain 7953) and *Bacillus atrophaeus* (NRRL No. B4418)

Mean population recovery: 1.0×10^5 to 5.0×10^5 colony forming units (cfu)/disc *Geobacillus stearothermophilus*
 1.0×10^6 to 5.0×10^6 cfu/disc *Bacillus atrophaeus*

Growth media: Specially modified soybean casein digest growth medium with pH indicator.

***D-Value for saturated steam (D_{121}):** greater than or equal to 1.5 minutes. D_{121} is determined with a 250°F (121°C $\pm 0.5^\circ\text{C}$) exposure temperature utilizing a prevacuum cycle.

***D-value for ethylene oxide (D_{EO}):** greater than or equal to 2.8 minutes

D_{EO} is determined with a 600 ± 30 mg/L ethylene oxide concentration, 129°F ($54^{\circ}\text{C} \pm 1^{\circ}\text{C}$) and 50-70% relative humidity.

**D-value is only reproducible under exact test conditions used in original text.*

Incubation temperature: $131\text{-}138^{\circ}\text{F}$ ($55\text{-}59^{\circ}\text{C}$) after steam sterilization cycles

$95\text{-}102^{\circ}\text{F}$ ($35\text{-}39^{\circ}\text{C}$) after ethylene oxide sterilization cycles

Shelf life: 12 months from time of manufacture. The expiration date is printed on the certification card that accompanies the VERIFY Dual Species SCBI and on the vial label (the lot number is the expiration date).

Quantity: 2 x 50 count boxes - S3060

1 x 50 count box - S3061

DIRECTIONS FOR USE

See the instruction card enclosed in the box of VERIFY Dual Species SCBI for detailed use directions.

After sterilization has been completed (and aeration, if required), allow the SCBI to cool until safe to handle. If utilized in a process challenge device, such as a test pack, allow the test pack to cool first. Then remove the SCBI from the test pack. Observe the chemical process indicator on each vial label to verify the color change corresponding to the sterilization cycle; i.e., ethylene oxide turns the gas process exposure indicator to gold and steam turns the steam process exposure indicator to brown. If the chemical indicator is unchanged, exposure to the sterilization process may not have occurred.

If the chemical process indicator on the vial label changed to the proper color and the SCBI is cool to the touch, firmly seal the SCBI by the recommended technique shown in the instructions included in the box. The SCBI is properly sealed when the cap is pushed down to the second black bar on the vial label.

To activate, push or pull the SCBI completely through the restricted space on the base of the vial activator (S3075). The SCBI is properly activated when the growth medium is released from the crushed ampule and is in contact with the spore disc. Verify the spore disc is submerged in the media by gently tapping the SCBI bottom on a hard surface.

The activated SCBI is ready for placement into the incubator. The incubation temperature is $95\text{-}102^{\circ}\text{F}$ ($35\text{-}39^{\circ}\text{C}$) following an ethylene oxide cycle sterilization cycle. The incubation temperature is $131\text{-}138^{\circ}\text{F}$ ($55\text{-}59^{\circ}\text{C}$) following a steam sterilization cycle. Examine the biological indicator during the incubation period. If the media in the SCBI begins to show turbidity and/or color change from blue to yellow, sterility has not been achieved. If sterilization of the indicator was achieved, the SCBI shows no change during the incubation period; i.e., there is no turbidity and the growth media remains blue.

A specially designed incubator is available for use with the VERIFY Dual Species Self-Contained Biological Indicators. Please contact STERIS for more information.

STORAGE CONDITIONS

VERIFY Dual Species SCBIs should be stored at a controlled room temperature ($68\text{-}77^{\circ}\text{F}$ [$20\text{-}25^{\circ}\text{C}$]) and 30-60% relative humidity. Do not store in close proximity to steam or ethylene oxide processing areas. Avoid contact with, or storage near, sterilants or chemicals, e.g., any oxidizing or reducing agents such as formaldehyde, bleach, ammonia, etc. Do not use after the expiration date printed on the packaging.

DISPOSAL

VERIFY Dual Species Self-Contained Biological Indicators should be appropriately treated as standard microbiological waste, non-pathogenic species; e.g. a steam sterilization cycle at 250°F (121°C) for not less than 30 minutes can be used, incineration or other suitable means.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

Description	Quantity Per Box	Reorder Number
VERIFY Dual Species SCBI	2 boxes/50 SCBIs per box	S3060
VERIFY Dual Species SCBI	50 SCBIs	S3061
Vial Activator Set	1 activator	S3075

For further information, please contact:

STERIS[®]



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