

GENERAL DESCRIPTION

The Verify S3112 Self-Contained Biological Indicator (SCBI) is for use in monitoring common ethylene oxide (EO) sterilization processes. The Verify S3112 SCBI is tested in accordance with International Standards Organization (ISO) 11138 and EN 866.

Each indicator is completely self-contained, combining a disc inoculated with a single spore species (*Bacillus atrophaeus*, NRRL#B4418) and an ampule of specifically modified soybean casein digest growth medium with pH indicators. The Verify S3112 SCBI is designed to be sealed after processing, reducing the risk of contamination (and consequent false positives) or growth medium evaporation.

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

The Customer can perform a reduced incubation time validation study and shorten holding time for product release. (All testing to determine reduced incubation time must be performed according to the U.S. Food and Drug Administration [FDA] Guide for Validation of Biological Incubation Time.) Sufficient growth medium is provided for incubation up to seven days, if desired.

APPLICATION

The Verify S3112 SCBI is designed and validated for use in monitoring the effectiveness of common ethylene oxide (EO) gas sterilizing processes. The Verify S3112 SCBI is for scientific applications and international use and is not approved for use in healthcare facilities in the United States.

FEATURES

- Bacillus atrophaeus*
single species E6 population
- Complies with performance requirements of ISO 11138-2 and EN 866-2
- Manufactured to meet current United States Pharmacopeia (USP)
- Reduced incubation time
- Chemical indicator on label
- Closed system after the Verify cap is pressed down
- Vivid color change of pH indicator during incubation to indicate microbial growth
- Complete system is self-contained, including BI, media and pH indicator
- Convenient dispenser box

BENEFITS

- E6 may be used in applications requiring a 6-log reduction
- Allows for harmonization of biological indicators between global Customer sites
- Compliance with current guidelines
- A reduced incubation time study may be performed by the Customer to shorten holding time for product release
- Provides immediate proof of processing
- Prevents contamination of vial contents. Media does not evaporate if incubated for seven days
- pH indicator makes positives easier to identify
- Reduces chances for false positives due to poor aseptic transfer technique
- Ease of use

TECHNICAL PROPERTIES

Spore carrier type: filter paper

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

Species: *Bacillus atrophaeus*, NRRL#B4418

Mean population recovery: 1.0×10^6 to 5.0×10^6 colony forming units (cfu)/disc

Growth media: Specially modified soybean casein digest growth medium

D-value for ethylene oxide (D_{EO}): 3.0 - 5.8 minutes

D_{EO} is determined with a 600 ± 30 mg/L ethylene oxide concentration, 54° (129°F) \pm 1°C, 50-70% relative humidity (RH) and an Oxyfume® 2000 sterilant¹ blend.

Incubation temperature: 35-39°C (95-102°F)

Shelf life: 12 months from time of manufacture. The expiration date is printed on the certification card that accompanies the Verify S3112 SCBI.

Quantity: 100 count box

DIRECTIONS FOR USE

After sterilization and aeration processing has been completed according to the sterilizer manufacturer's instructions, allow the test packs to cool until they are safe to handle and open. Remove the Verify S3112 SCBI from the test pack. Observe the chemical process indicator on the vial label to verify the EO process indicator has turned gold. 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 Verify S3112 SCBI is cool to the touch, firmly seal the Verify S3112 SCBI by the recommended technique shown in the instructions included in the Verify S3112 SCBI box. The Verify S3112 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 Verify S3112 SCBI completely through the restricted space on the base of the Verify Vial Activator (S3075). The Verify S3112 SCBI is properly activated when the growth medium is released from the crushed ampule and is in contact with the spore disc. It is not necessary to shake or invert the activated Verify S3112 SCBI after removal from the activator.

The activated SCBI is ready for placement into the 35-39°C (95-102°F) incubator. Examine the biological indicator during the incubation period. If the media in the Verify S3112 SCBI begins to show turbidity and/or color change from deep blue to yellow, sterility has not been achieved. If sterilization of the indicator was achieved, the Verify S3112 SCBI shows no change during the incubation period; i.e., there is no turbidity and the growth media remains deep blue.

See the instruction card enclosed in the Verify S3112 SCBI box for detailed use directions.

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

STORAGE CONDITIONS

Verify S3112 SCBIs should be stored at controlled room temperature 20-25°C (68-77°F) as defined by the USP and a relative humidity of 30-80%. 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

Before discarding, treat as appropriate for standard microbiological waste, nonpathogenic species.

1. Oxyfume® 2000 is a registered trademark of Honeywell.

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	Reorder Number
Verify S3112 Self-Contained Biological Indicator	100 per box	S3112
Verfiy Vial Activator Set	1	S3075

For further information, please contact:

STERIS[®] STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.steris.com