

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.

Each indicator is completely self-contained, combining a disc inoculated with a single spore species (*Bacillus atrophaeus*, NRRL#B4418) and an ampule of specially 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 (CI) on each vial provide immediate proof of processing. Following incubation, a vivid color change from deep blue to yellow and/or solution becomes turbid gives unmistakable evidence of microbial growth. If no microbial growth occurs, the vial remains deep blue without turbidity.

APPLICATION

The VERIFY S3112 SCBI is designed and validated for use in monitoring the effectiveness of common ethylene oxide gas sterilizing processes. The VERIFY S3112 SCBI is for scientific applications in the United States and International markets and is not cleared for use in healthcare facilities in the United States.

FEATURES

Bacillus atrophaeus single species E6 population

Conforms with performance requirements of ISO 11138-1 and 11138-2

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, pH indicator, and CI

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

Allows readout at 48 hours incubation

Provides immediate proof of processing

Prevents contamination of vial contents; media does not evaporate when incubated for seven days

pH indicator makes positives easier to identify

Reduces chances for false positives due to errors in 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

pH indicators: bromthymol blue and bromocresol purple

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°C (129°F) \pm 1°C and 50-70% Relative Humidity (RH).

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. See Instructions For Use. The lot number is also the expiration date in the format yymmdd with Ba to denote the indicator organism.

Quantity: 100 count box

DIRECTIONS FOR USE

After sterilization and aeration processing has been completed according to the sterilizer manufacturer's instructions, allow the SCBIs to cool until they are safe to handle. 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 box of the VERIFY S3112 SCBI. 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 becomes turbid 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 color 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 box of the VERIFY S3112 SCBI 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) and a relative humidity of 30-60%. Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents like 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. Generally, this consists of autoclaving at 121°C (250°F) for 30 minutes or direct exposure to an oxidative sterilant; e.g., Spor-Klenz® Ready-to-Use Cold Sterilant, Spor-Klenz® Concentrate Cold Sterilant, or 500 ppm sodium hypochlorite for 30 minutes.

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 S3112 Self-Contained Biological Indicator	100	S3112
VERIFY Vial Activator Set	1	S3075
VERIFY Incubator *		

* Contact Customer Service for appropriate reorder number for your region.

For further information, please contact:



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