



Product Technical Data Sheet

Form No.: FTP-108 Rev.: C

Product Name: SteriTec EZTest EO Biological Indicators

Product Type: Biological Indicator

SteriTec Reorder Number: EZEO/100/CS (100 Box) or EZEO/25/CS (25 Box)

Description: The SteriTec EZTest EO Biological Indicator was designed to provide a sterilization challenge and placement in an ethylene oxide sterilization challenge pack as defined by AAMI ST41. The Biological Indicator consists of a plastic vial with an inoculated spore strip and sealed glass vial containing media placed inside. The outer vial is sealed with a plastic cap and filter paper. Small orifices in each cap provide for steam penetration. When the glass vial is crushed, the growth media flows onto the inoculated spore strip. The vial is then incubated and, if viable spores are present, the media color will change color.

Performance Characteristics:

After exposure to ethylene oxide, the biological indicator, when incubated, will indicate either growth or no growth.

Color Change: BI Indicator Stripe = Red to Yellow

BI Growth Medium = Red to Yellow with growth

Complete Kill Time: 30-45 min. at 600 mg/l, 45% RH, 130°F.

Indicator Stability: Chemical indicator – Before and After Exposure = Excellent
Biological Media Color = 72 hours

Physical Characteristics:

Dimensions: 1.9" L X .4" D

Chemical Indicator Substrate Material: Process Indicator = Label Stock

Biological Indicator: Bacillus atrophaeus

Incubation Temperature/Time: 35°-39°C, 48 hours

Quantity / Box: 100 or 25

Boxes / Case: 4 (100 Box) or 8 (25 Box)

Selling Unit: Case

Environmental Limitations:

Storage: 50° - 100°F (10° - 38°C) at 20 - 70% humidity

Shelf Life: The expiry date is printed on the product packaging.

FDA 510(k) Release to Market Date: SGM Biotech 510(k)

Standards Classifications:

Process Indicator Label

ANSI/AAMI ST79, Class 1

ISO 11140-1, Class 1

Biological Indicator

ANSI/AAMI/ISO 11138