



Product Technical Data Sheet

Form No.: FTP-107 Rev.: C

Product Name: SteriTec EZTest Steam Biological Indicators

Product Type: Biological Indicator

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

Description: The SteriTec EZTest Steam Biological Indicator was designed to provide a sterilization challenge and placement in a 16-towel pack as defined by AAMI ST46. 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 steam, the biological indicator when incubated will either indicate growth or no growth.

Color Change: BI Indicator Stripe = Blue to Black

BI Growth Medium = Purple to Yellow with growth

Complete Kill Time: 25 minutes at 121°C.

Indicator Stability: Chemical indicator – Before and After Exposure = Excellent

Biological Media Color = 72 hours

Physical Characteristics:

Dimensions: 1.9" L X .4" D

Indicator Substrate Material: Process Indicator = Label Stock

Biological Indicator: *Geobacillus stearothermophilus*

Incubation Temperature/Time: 55°-60°C/ <24 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:

ANSI/AAMI/ISO 11138