



## Product Technical Data Sheet

Form No.: FTP-012 Rev.: E

### Product Name: SteriTec EO Gas Biological Test Pack with Instant Readout Integrator

**Product Type:** Biological Indicator

**Reorder Number:** BI 102

**Description:** The SteriTec EO Gas Biological Test Pack with Instant Readout Integrator was designed specifically for biological testing of EO Gas sterilizers. The objective is to simulate a biological indicator placed in the most difficult product being sterilized in a load. The Test Pack simulates the biological test pack as defined by AAMI for the evaluation of ethylene oxide sterilizers. Each disposable test pack contains a self contained biological indicator, placed inside a diffusion resistant plastic container and covered with a closure cap, and then placed in a paper peel pouch with a instant readout integrator card. The Instant Readout Integrator Card gives a prediction of the biological test outcome.

#### Performance Characteristics:

When exposed to EO gas sterilization cycles, the word "PASS" on the Instant Readout Integrator Card will change color. The biological indicator, when incubated, will indicate either growth or no growth.

**Color Change:** Instant Readout Integrator Card = Yellow to Brown at 60 minutes with 600 mg/l EO gas, 40-60% RH, 130° F. BI Indicator Stripe = Blue to Brown. BI Growth Medium = Red to Yellow with growth

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

**Incubation Time:** 48 hours at 35° – 39° C

**Indicator Stability:** Integrator Card – Excellent before and after sterilization.  
Biological Media Color – 72 hours.

#### Physical Characteristics:

**Dimensions:** Integrator Card - 2.5" W X 4" L. Pouch – 3.5" X 10"

**Integrator Card Substrate Material:** Bio Index

**Biological Indicator:** Bacillus atrophaeus

**Quantity / Pouch:** 1

**Pouches / Case:** 30 plus 5 control biological indicator vials

**Selling Unit:** Case

#### Environmental Limitations:

**Storage:** 60° - 90° F (15° – 30° C) at 20 – 70% humidity.

**Shelf Life:** 24 months from date of manufacture.

**FDA 510(k) Release to Market Date:** October 29, 1998. K981497

#### Standards Classifications:

*Instant Readout Integrator Card*

AAMI ST60, Class 5

EN 867-1, Class D

ISO 11140-1, Class 5

*Test Pack*

AAMI ST60, Class 2

EN 867-1, Class B

ISO 11140-1, Class 2

*Biological Indicator*

AAMI ST59, 1999