



## Product Technical Data Sheet

Form No.: FTP-044 Rev.: K

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

**Product Type:** Biological Indicator

**Reorder Number:** BI 103 (for USA distribution)  
BI 103/10 (for USA distribution)  
BI 103/30 (for USA distribution)

**Description:** The SteriTec Steam Biological Test Pack with Instant Readout Integrator Card was designed to provide the same resistance to steam as a 16-towel pack as defined by ANSI/AAMI ST79. The objective is to simulate a biological indicator placed in a large hospital pack and sterilized. Each disposable Test Pack contains an EZTest® (manufactured by SGM BioTech) self-contained biological indicator, an Instant Readout Integrator Card and several index sheets for steam penetration resistance simulation. The Test Pack was designed to function in a 132°C pre-vacuum steam sterilizer. The Instant Readout Integrator Card gives a prediction of the biological test outcome, especially helpful for hospital determinations regarding early release.

#### Performance Characteristics:

When exposed to steam sterilization cycles, the chemical indicator printed on the Instant Readout Integrator (PASS) will change from purple to green, indicating an acceptable sterilization process and biological kill. The biological indicator, when incubated, will indicate either growth or no growth.

**Color Change:** Instant Readout Integrator = Purple to Green.

BI Indicator Stripe = Blue to Black

BI Growth Medium = Purple to Yellow with growth

**Critical Parameters:** (in a standard hospital pre-vacuum steam sterilizer)  
3 minutes at 132°C.

**Stated Values:** (Integrator card only, not in a pack, as determined in a steam resistometer)  
5 minutes (+0/-45 seconds) @ 132°C (+0/-1°C)

**Incubation Time:** 24 hours at 55° – 60°C

**Indicator Stability:** Instant Readout Integrator Card – Excellent Before and After sterilization.  
Biological Media Color – 72 hours

#### Physical Characteristics:

**Dimensions:** 2.47" W X 3.97" L

**Substrate Material:** Instant Readout Integrator Card = Print Blotter. Resistance Sheets = Bio Index

**Biological Indicator:** *Geobacillus stearothermophilus*

**Quantity / Box:** 1

**Boxes / Case:** 30 plus 5 control biological indicator vials (BI 103)

30 plus 10 control biological indicator vials (BI 103/10)

30 plus 30 control biological indicator vials (BI 103/30)

**Selling Unit:** Case

#### Environmental Limitations:

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

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

**FDA 510(k) Release to Market Date:** May 15, 2000, K001444 (for US version only)

#### Standards Classifications:

Biological Indicator: ANSI/AAMI/ISO 11138

Test Pack: ANSI/AAMI ST79