



# Product Technical Data Sheet

Doc. No.: FTP-298 Rev.: D

## Product Name: SteriTec Smart-Read Biological Test Pack with Instant Readout Integrator

**Product Type:** Biological Indicator

**SteriTec Reorder Numbers:** BI 108 (with 5 Controls), & BI 108/30 (with 30 Controls)

**Description:** The Smart-Read® Biological Test Pack with Instant Readout Integrator 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® 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 (270° F) pre-vacuum steam sterilizer. The Instant Readout Integrator Card gives a prediction of the biological test outcome that is especially helpful for hospital determinations regarding early release. Also, the Test Packs are available with either 5 or 30 biological indicators for use as positive controls.

### 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 demonstrate 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 steam sterilizer)

3 minutes at 132°C

**Stated Values: (as determined in a steam resistometer)**

Indicator Card – 5.5 minutes (+0/-46 sec.) at 132°C (+0/-1°C); (270° F +32/-33.8°F)

**Incubation Time:** If sterilization failure occurs, Smart-Read will provide positive biological evidence of that failure within 5 hours of incubation. A positive test can be immediately confirmed by the operator visually observing the color change to yellow. To meet the USFDA/RIT protocol the biological indicator may be further incubated for a total of 10 hours.

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

### Physical Characteristics:

**Dimensions:** 2.5" W X 4" L

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

**Biological Indicator:** 10<sup>5</sup> Geobacillus stearothermophilus

**Quantity / Box:** 1

**Boxes / Case:** 30 Test Packs plus 5 or 30 control biological indicator vials

**Selling Unit:** Case

### Environmental Limitations:

**Storage:** 50° - 100°F (10° – 38°C) at 10 – 60% humidity

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

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

### Standards Classifications:

Biological Indicator: ANSI/AAMI/ISO-11138

Test Pack: ANSI/AAMI ST79

Test Card: FDA Integrator