



Product Technical Data Sheet

Form No.: FTP-044-1 Rev.: F

Product Name: SteriTec International Biological Test Pack with Instant Readout Integrator and 5 Controls

Product Type: Biological Indicator

Reorder Number: BI 103/INT

Description: The SteriTec International Biological Test Pack with Instant Readout Integrator Card was designed as a process challenge device (PCD) 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 PCD was designed to function in a 132° -134°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 Card (PASS) will change from purple to green (endpoint), 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 or longer at 132° -134°C (endpoint)

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)

4.5 minutes (+0/40 seconds) @ 134°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

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

Test Card: FDA Integrator

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