

TBI 004 – SPORE STRIPS *Geobacillus stearothermophilus*

INTENDED USE

Biological Indicator for Low-temperature Steam and Formaldehyde Sterilization Pack- TBI 004

PRODUCT FEATURE

Biological Indicators for monitoring Low-temperature Steam and Formaldehyde Sterilization consist of:

- A filter paper which inoculated spores of *Geobacillus stearothermophilus* ATCC7953 with a population level of $\geq 10^5$
- A breathing envelope (Tyvek®) as the primary packaging of the product, which can protect from pollution. The TBI 001 culture medium is supplied in individual tubes for easy aseptic transfer and culturing. This medium offers the advantage of a 48-hour reduced incubation time. Test results are obtained during incubation by observing the medium which changes color from purple to or toward yellow and/or turbid if any spores have survived the process.

INDICATION FOR USE

The TBI 004 are designed specifically for the pharmaceutical, food, and medical device industries utilizing LTSF sterilization.

PERFORMANCE CHARACTERISTICS

Population	1×10^5 to 1×10^7 CFU/pcs	
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.	
Resistance	D value	≥ 1.5 mins
	RIT	$\geq 97\%$
	Test condition: 60 ± 0.5 °C, FORM 1.0 ± 0.01 mol/L.	

TECHNICAL INFORMATION

- Color of culture medium** : Positive (Yellow color); Negative (Purple color).
- Quality of culture medium** : 3.0-3.5 ml
- Weight of BI** : 0.35-0.4 g/pcs
- Period of validity** : 36 months
- Dimensions** : Envelope: 30mm×63mm TBI 004 : 15.0 mm (diameter)*103mm (height)



COMPLIANCE

ISO 11138-1:2017 Sterilization of health care Products-Biological Indicators-Part1: General requirements.
ISO 11138-5:2017 Sterilization of health care Products-Biological Indicators-Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes.
BI Premarket Notification[510(k)], Submissions, issued October 4, 2007.

PACKAGING

300pcs/box Nos

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

*For Lab Use Only
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