

Product Name and Code:

Biological Indicator For Low-temperature Steam and Formaldehyde sterilization processes – **LBF144**

Product Description:

Self-Contained Biological Indicators consist of:
 A plastic pipe and cap. The cap with a hole is placed on top of the pipe to allow the sterilizing agent to penetrate into the indicator. Between pipe and cap there is a filter paper which is used to avoid pollution. A crushable media ampule which contains modified culture medium with a pH indicator. The modified culture medium will change from the initial Purple color to Yellow in the presence of bacterial growth. An inoculated carrier of *Geobacillus stearothermophilus* ATCC 7953 is located at the bottom closed end of the pipe.

The LBF144 Biological Indicator, when used with an incubator (incubation temperature 56-60°C), provides a test result in a short period (24 hours) with an accuracy of $\geq 97\%$.

The label on the outside of the plastic pipe contains a Type 1 chemical indicator strip.



Indications for use:

The LBF144 is utilized to monitor the Formaldehyde Sterilization Processes.

Performance characteristics:

Population	3X10 ⁵ to 1X10 ⁷ CFU/pcs	
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.	
Resistance	D value / m	6 ~ 10
	Survival / m	18 ~ 50
	Kill / m	60 ~ 100
	RIT	$\geq 97\%$
Test condition: 60 °C ± 0.5 °C , FORM 1.0 ± 0.01 mol/L		

Technical information:

Label color change	Before: red; After: green;
Color of culture medium	Positive: yellow; Negative: purple;
Quality of culture medium	0.5-0.6ml
Weight of BI	2.1-2.2g/pcs
Period of validity	36 months
Dimensions	10.9 mm (cap diameter) 8.8 mm (pipe diameter) 46 mm (height)

Compliance:

ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: 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.
 ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

Package:

LBF144: 100 pcs/box

Version: 20250218

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