

Product Name and Code:

Ultra Super Rapid Biological Indicator For Low-temperature Steam and Formaldehyde sterilization processes – **LBF020**

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 and fluorogenic substrates. 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 LBF020 Rapid Biological Indicator, when used with an automatic reader (incubation temperature 56-60°C), provides a fluorescence test result in a short period (20 minutes) with an accuracy of $\geq 97\%$. As an option the user can continue the incubation for 48 hours in order to confirm visually the stability or color change of the culture medium.

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



Indications for use:

The LBF020 is utilized to monitor the Formaldehyde Sterilization Processes.

Performance characteristics:

Population	1 X 10 ⁶ to 2 X 10 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	

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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	2.3-2.4g/pcs
Period of validity	24 months
Dimensions	10.9 mm (cap diameter) 8.6 mm (pipe diameter) 57 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:

LBF020: 50pcs / box

Version: 20240627

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