

Product Name and Code:

Biological Indicator For plasma or vaporized Hydrogen Peroxide sterilization processes – **LBH288**

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 LBH288 Biological Indicator, when used with an incubator (incubation temperature 56-60°C), provides a test result after 48 hours.

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



Indications for use:

The LBH288 is utilized to monitor the efficacy of H₂O₂ plasma sterilization cycles.

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 / s	5 ~ 80
	Survival / s	100 ~ 300
	Kill / s	100 ~ 800
	RIT	≥97%
	Test condition: 50 °C ± 0.5 °C , H ₂ O ₂ 2.3 ± 0.4 mg/L	

Technical information:

Label color change	Before: green; After: yellow;
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.
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:

LBH288: 100 pcs/box

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