

Product Name and Code:

Biological Indicator For Steam sterilization processes –
LBS144

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 LBS144 Biological Indicator, when used with an incubator (incubation temperature 56-60°C), provides a test result after 24 hour 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 LBS144 is utilized to monitor steam sterilization processes efficacy at 121°C to 135°C.

Performance characteristics:

Population	3X10 ⁵ to 5X10 ⁶ CFU/pcs	
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.	
Resistance	121°C D value/m	1.5 to 4min
	121°C Survival/m	5 to 15min
	121°C Kill/m	18 to 40min
	132°C D value/m	0.15 to 0.7min
	134°C D value/m	0.1 to 0.6min
	Z value	8 to 30°C
	RIT	$\geq 97\%$
Test condition: 121 °C; 132 °C; 134 °C; Saturated steam with pre-vacuum		

Technical information:

Label color change	Before: pink; After: black;
Color of culture medium	Positive: yellow; Negative: purple;
Quantity 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 11138-3:2017 Sterilization of healthcare products-Biological indicators-Part 3 Biological indicators for moist heat sterilization processes.

ISO 11138-8:2021 Sterilization of healthcare products-Biological indicators-Part 8 Method for validation of a reduced incubation time for a biological indicator.

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

Package:

LBS144: 100 pcs/box

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Manufactured by: LISTER BIOMEDICAL CO.,LTD.
Building 2, No.72 Shengli Road, Yixiu, Anqing, Anhui, China.
Tel. +86 556 5689070
E-mail: info@listerbiomed.com -www.listerbiomed.com