

## Product Name and Code:

Biological Indicator For Ethylene Oxide Sterilization Processes – **LBE288**

## 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 transition from the initial Blue color to Yellow in the presence of bacterial growth. An inoculated carrier of *Bacillus atrophaeus* ATCC 9372 is located at the bottom closed end of the pipe.

The Biological Indicator, when used with an incubator (incubation temperature 35-39°C), provides a biological culture result after 48 hours.

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



## Indications for use:

The LBE288 is utilized to monitor EO sterilization process efficacy.

## Performance characteristics:

<b>Population</b>	1X10 <sup>6</sup> to 1X10 <sup>7</sup> CFU/pcs	
<b>Purity</b>	No evidence of contamination present in sufficient numbers to adversely affect the finished product.	
<b>Resistance</b>	<b>D value / m</b>	2 ~ 6
	<b>Survival / m</b>	8 ~ 25
	<b>Kill / m</b>	20 ~ 60
	<b>RIT</b>	≥97%
	Test condition: 54 °C ± 1 °C, 60% RH ± 10% RH, 600 mg/L ± 30 mg/L 100%EO	

**Technical information:**

<b>Label color change</b>	Before: pink; After: brown;
<b>Color of culture medium</b>	Positive: yellow; Negative: green;
<b>Quality of culture medium</b>	0.5-0.6ml
<b>Weight of BI</b>	2.1-2.2g/pcs
<b>Period of validity</b>	36 months
<b>Dimensions</b>	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 11138-2:2017 Sterilization of health care products-Biological indicators-Part 2: Biological indicators for ethylene oxide 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:**

LBE288: 100 pcs/box

**Version: 20250218**