

# SELF - CONTAINED BIOLOGICAL INDICATOR 4 HOUR READOUT SYSTEM RAPID



4 hours

For ethylene oxide sterilization processes

EO

## Usage

Monitoring of sterilization cycles by Ethylene Oxide.

## Characteristics

**Rapid Readout: By Fluorescence in 4 hours.**

Fluorescence is a direct measure of Bacillus Atrophaeus spores viability that have resisted the sterilization process (positive result). Rapid readout must performance in auto-reader Smart Incubator<sup>®</sup> set at the incubation temperature of 37°C and final readout of 4 hours. Optionally, the incubation period can be extended for 48 hours to obtain the result by changing the color of the culture medium if the result is positive (colorimetry).

- $\geq 10^7$  Bacillus Atrophaeus ATCC 9372 spores per vial.
- D-Value: Not lower than 2.5 min (600mg/l, 54°C, 60%HR).

## Shelf-life

24 months

## Presentation

Package by 50 units

## Applicable regulation

ISO 11138

## Authorization and habilitation

ANMAT: PM 1454-45

## Classification

Class 1, according to risk

## Certification

ISO 9001:2015

ISO 13485:2016

GMP by ANMAT (Argentinean National Administration of Drugs, Food and Medical Devices)

**Exclusive sale to Professionals  
and Health Institutions**

## Storage

Store the ESTERCONT indicators to room temperature (5°C – 45°C).  
Don't store near the sterilizing agents or others chemicals.

## Transportation conditions

Storage conditions must be followed  
Transport should be in closed boxes and reinforced to avoid damage.  
The transport of this product is not a risk for the human health.

## Precautions

Do not use the biological indicator to control sterilization processes by Steam, Dry Heat, Radiation or other process different from Ethylene Oxide sterilization. Read the instructions before using biological indicator.

## Labelling

Package: manufacturer details, reference code, product description, process for which it is used, presentation, classification according to regulations, bacterial strain, date of manufacture and expiry date.

On product: Black printed label of material suitable for the sterilization process, 1.5 mm chemical indicator line printed with Ethylene Oxide reactive ink, batch number, expiration date, process for intended use and bacterial strain.

## Compability

Compatible with any type of 4-hour rapid readout incubator for ethylene oxide. It is recommended to incubate in the Smart Incubator®.