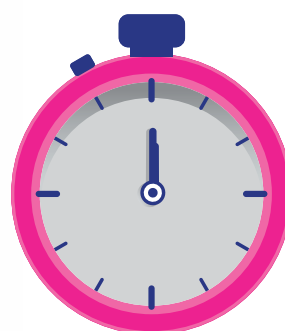


SELF –CONTAINED BIOLOGICAL INDICATOR

ETHYLENE OXIDE



48 hours

E0

Usage

Monitoring of sterilization cycles by ethylene oxide.

Characteristics

Conventional readout: 48 Hours by Colorimetry.

Incubation should be carried out in a conventional incubator set at the incubation temperature of 37 ° C. The color change of the culture medium to yellow at any time within 48 hours of incubation is a direct measure of the germination and growth activity of *Bacillus Atrophaeus* spores that have resisted the sterilization process (positive result). If the color of the culture medium remains red after 48 hours of incubation, the sterilization process was successful.

- $\geq 10^6$ *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 100 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: Green 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.

Compatibility

Compatible with any type of 48-hour readout incubator for Ethylene Oxide.