

# SELF-CONTAINED BIOLOGICAL INDICATOR STEAM

## Rapid One



1 hour

STEAM

### Usage

Monitoring vacuum assisted for steam sterilization cycles at 121°-134°C and for gravity air-displacement for Steam sterilization cycles at 121-134°C

### Characteristics

#### Rapid Readout: By Fluorescence in 1 hour.

Fluorescence is a direct measure of *Geobacillus stearothermophilus* 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 55-57°C and with final readout of 1 hour. Optionally, the incubation period can be extended for 24 hours to obtain the result by changing the color of the culture medium if the result is positive (colorimetry).

- $\geq 10^6$  *Geobacillus stearothermophilus* ATCC 7953 spores per vial.
- D-Value: Not lower than 1.5 minutes at 121 °C.
- Z-Value: Not lower to 6 °C

### 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 EO, Dry Heat, Radiation or other process different from Steam 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 Steam reactive ink, batch number, expiration date, process for intended use and bacterial strain.

## Compatibility

Compatible with any type of 1-hour rapid readout incubator for Steam. It is recommended to incubate in the Smart Incubator®.