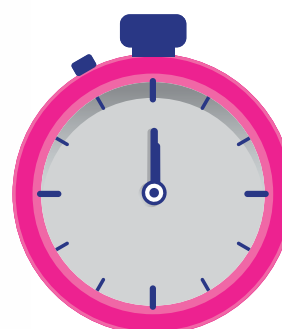


SELF – CONTAINED BIOLOGICAL INDICATOR

STEAM



24 hours

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

Conventional readout: 24 Hours by Colorimetry.

Incubation should be carried out in a conventional incubator set at the incubation temperature of 55-57 ° C. The color change of the culture medium to yellow at any time within 24 hours of incubation is a direct measure of the germination and growth activity of *Geobacillus stearothermophilus* spores that have resisted the sterilization process (positive result). If the color of the culture medium remains purple after 24 hours of incubation, the sterilization process was successful.

- $\geq 10^5$ or $\geq 10^6$ *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 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 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 24-hour readout incubator for Steam.