

Infection Control Division | Biological Indicators

## BT10 Self-Contained Biological Indicator For ethylene oxide sterilization processes



### Usage

Monitoring ethylene oxide sterilization processes.

### Applicable regulation

Designed under Quality Management System standards ISO 13485:2016 / EN ISO 13485:2016.

ISO 11138-1:2017, ISO 11138-2:2017, ISO 11138-8:2021 and ISO 11140-1:2014.

### Authorization

ANMAT (Argentinian National Administration of Drugs, Food and Medical Devices) PM 1614-1.

### Classification

Class 1, according to risk (ANMAT).

### Characteristics

Polypropylene tube: 45.2 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm

Polypropylene cap: 13.0 mm high x 10.9 mm external diameter. Wall thickness: 0.7 mm

Cap filter: medical grade paper, 17.0 mm diameter.

Glass ampoule: 35.0-40.0 mm high. External diameter: 6.5 mm. Wall thickness: 0.2-0.3 mm.

Culture medium 0.5-0.7 ml, blue color.

Spore carrier: filter paper, 7.0 mm diameter.

$\geq 10^6$  *Bacillus atrophaeus* ATCC\*\* 9372 spores per vial.

Positive growth results (failure in the sterilization process): culture medium turns to yellow, incubation at 37 °C for 48 hours (maximum).

D-value: not lower than 2.0 minutes.

Conditions: 600 ± 30 mg/l EO, 60 ± 10 % RH, 54 ± 1 °C.

### Environmental conditions during manufacture

T = 15-30 °C, RH = 30-80 %. Sterility conditions are necessary only during the inoculation process performed in laminar flow.

### Storage conditions

T = 10-30 °C, RH = 30-80 %, keep away from light.

### Transport conditions

Storage conditions should be strictly followed.

Products should be transported in closed and reinforced boxes in order to avoid damages. Product transportation does not represent any risk for human health.

### Shelf life

2 years.

\*ATCC® is a registered trademark of American Type Culture Collection.

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### Packing

30 or 100 units per box.

Packing information: product code and description, process for intended use, presentation, regulation, bacterial strain, storage conditions, manufacturer information and data on box's label.

### Labelling

On product's packing: product code, batch number, bacterial load, manufacture and expiration date, barcode and Data Matrix.

### Possible target markets

Healthcare and Industry.

### Other important information

It is advisable to incubate at 37 °C in Bionova® IC10/20 incubators. Read product's Instructions for Use thoroughly before use.

### Precautions

Do not store the product near sterilizing agents.

Do not use this product to control steam, hydrogen peroxide, dry heat, formaldehyde or any other sterilization process other than ethylene oxide.

Do not freeze.