

# BT100

## Self-contained Biological Indicator

For Formaldehyde sterilization processes.



### Usage

Monitoring Formaldehyde Sterilization Processes.

### Applicable Regulation

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

ISO 11138-1:2017 and ISO 11138-5:2017; IRAM 37102-1:1999.

### Classification

Class 1, according to risk.

### Authorization

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

### 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, 60.0 g/m<sup>2</sup>.

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, **purple** color.

Spore carrier: polyethylene fibers, 7.0 mm diameter, 64.5 g/m<sup>2</sup>.

10<sup>5</sup> or 10<sup>6</sup> *Geobacillus stearothermophilus* ATCC 7953 spores per vial.

Upon completion of sterilization process, incubate the indicator for a maximum of 48 hours, between 55-62 °C.

Positive growth results (failure in the sterilization process): culture medium turns to **yellow** after incubation between 55-62 °C for 48 hours (maximum).

D-Value<sub>FORM</sub>: not lower than 6.0 minutes at 60 °C, 1 mol/l Formaldehyde.

### 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 in a dark place.

### Transport conditions

Storage conditions should be strictly followed.

Products should be transported in closed and reinforced boxes in order to avoid damages.

The transport of this product does not represent any risk for human health.

### Shelf life

2 years.

### **Packing**

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 the product: 17.0 mm x 33.0 mm polypropylene label, printed in black. 1.5 mm chemical indicator line, printed with Formaldehyde reactive ink (color change to green). Product code, process for intended use, name of organism, batch number and expiration date.

On product's packing: product code, batch number, bacterial load, manufacture date, expiration date, bar code and datamatrix code.

Note: manufacture date is calculated by subtracting 2 years to the expiration date.

### **Possible target markets**

Healthcare and Industry.

### **Other important information**

It is advisable to incubate at 60 °C in Bionova® IC10/20 incubator.

Read product's directions for use thoroughly before use.

### **Precautions**

Do not store the product near sterilizing agents.

Do not expose this product to Steam, Dry Heat, Radiation or any sterilization process other than Formaldehyde.