

# BT60

## Dual Spore Strips Biological Indicator

For Ethylene Oxide (EO), Steam and Dry Heat sterilization processes.



### Usage

Monitoring Ethylene Oxide, Steam, and Dry Heat Sterilization Processes.

### Applicable regulation

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

ISO 11138-1:2017, ISO 11138-2:2017, ISO 11138-3:2017 and ISO 11138-4:2017; IRAM 37102-1:1999, IRAM 37102-2:1999 and IRAM 37102-3:1999.

### Authorization

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

### Classification

Class 1, according to risk (ANMAT).

### Characteristics

25 mm x 70 mm non-absorbent material package, Violet code.

5 mm x 25 mm filter paper strips.

$10^5$  or  $10^6$  *Geobacillus stearothermophilus* ATCC 7953 spores and  $10^6$  *Bacillus atrophaeus* ATCC 9372 spores per strip.

Upon completion of the sterilization cycle, the spore strip should be tested in a suitable culture medium at 37 °C or at 60 °C. We suggest the use of BIONOVA® MC1020 or MC1030 culture media to final reading in 48 hours at 37 °C for Ethylene Oxide and Dry Heat sterilization process control, or BIONOVA® MC20 or MC1020 culture media to final reading in 24 hours at 60 °C for Steam sterilization process control. For conventional culture media like TSB, incubation for 7 days is recommended.

D-Value<sub>STEAM</sub>: Not lower than 1.5 minutes. Conditions: 121 °C.

Z-Value<sub>STEAM</sub>: Not lower than 6 °C.

D-Value<sub>EO</sub>: Not lower than 2.0 minutes. Conditions: 600 mg/l EO (100%), 60 % RH, 54 °C.

D-Value<sub>DRY HEAT</sub>: Not lower than 2.0 minutes. Conditions: 160 °C.

Z-Value<sub>DRY HEAT</sub>: Not lower than 20 °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 %.

### 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 bag.

**Labelling**

On product's envelope: product code and description, process for intended use, batch number, expiration date, bacterial strain and datamatrix code.

On product's packing: code and description of the product, process for intended use, strain and population of bacteria, batch number, manufacture and expiration date, presentation, regulation, storage conditions, manufacturer information, barcode and datamatrix code.

**Possible target markets**

Healthcare and Industry

**Other important information**

It is advisable to incubate at 37 °C or at 60 °C in Bionova® IC10/20 incubator.

Read product's instructions for use thoroughly before use.

**Precautions**

Do not store the product near sterilizing agents.

Do not expose this product to radiation, H<sub>2</sub>O<sub>2</sub> or any sterilization process other than EO, Steam and/or Dry Heat.