BT102

Self-Contained Biological Indicator

Rapid Readout Fluorescence System.

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

Authorization

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

Classification

Class 1, according to risk (ANMAT).

Characteristics

Polypropylene tube: 50.7 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm
Polypropylene cap: 16.4 mm high x 10.7 mm external diameter. Wall thickness: 0.9 mm
Cap filter: polyethylene fibers, 17.0 mm diameter.
Glass ampoule: 35.0 – 40.0 mm high. mm. External diameter: 6.8 mm. Wall thickness: 0.2 – 0.3 mm.
Culture medium 0.5 – 0.7 ml, purple color.
Polypropylene microfiber on spore carrier, 17.0 mm diameter.
Spores carrier: polyethylene fibers, 17.0 mm of diameter.
≥ 10^6 *Geobacillus stearothermophilus* ATCC 7953 spores per vial.

Final fluorescence reading is performed after 2 hour-incubation at 60 °C (sensitivity: 97 %).
An optional visual pH color change confirmation could be made after 48 hours of incubation. If sterilization process has not been successful, culture medium will change to a greenish color first, and then to yellow during incubation at 60 °C, thus showing the presence of living spores. If sterilization process is successful culture medium will remain purple after the incubation process.
7-day readout is optional and not intended to be routinely performed; it is an initial validation of the 2 hour-reading. Fluorescence results may be compared to the 7-day visual reading.
NOTE: If 7-day readout is performed, a humidified environment will be required to avoid medium to dry out.
D-Value$_{FORM}$: not lower than 6 minutes at 60 ºC, 1 mol/l Formaldehyde.

Environmental conditions during manufacture

T= 15-30 °C, RH 30-80 %. Sterility conditions are necessary only during 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

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

Labelling

On 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 and description, 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 ºC in Bionova® IC10/20FR, IC1020FRLCD or MiniBio Auto-Reader incubators.
Read product's instruction 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.