

BT80

Self-contained Biological Indicator.

For Moist Heat decontamination processes.



Usage

Control of medical waste decontamination processes through Moist Heat, by means of radio frequency and/or microwave radiation.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016. ISO 11138-1:2017 and 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: 45.2 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.

Polypropylene cap: 13.0 mm high x 10.6 mm external diameter. Wall thickness: 0.9 mm.

Cap filter: medical grade paper, 17.0 mm diameter.

Glass ampoule: 35.0 - 40.0 mm high. External diameter: 6.8 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.

10^4 *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 at 95 °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 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 product: 17.0 mm x 33.0 mm polypropylene label. Printed in black. Product code, batch number, expiration date, intended use and name of organism.

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

NOTE: manufacture date is calculated by subtracting 24 months to the expiration date.

Possible target markets

Healthcare and Industry.

Other important information

It is advisable to incubate at 37 °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 EO, Steam, Dry Heat, Radiation or any sterilization processes other than Moist Heat produced by microwaves or radio frequency.