

Infection Control Division | Biological Indicators

BT30 Semi Self-Contained Biological Indicator For dry heat sterilization processes



Usage

Monitoring dry heat sterilization processes at 160-180 °C.

Applicable regulation

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

ISO 11138-1:2017, ISO 11138-4:2017 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

Tube A: Nylon tube. 45.0 mm high x 8.4 mm external diameter. Wall thickness: 1.0 mm.

Tube B: Polypropylene random copolymer tube. 45.2 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.

Cap A: Nylon cap. 10.5 mm external diameter, 13.1 mm high. Wall thickness: 1.2 mm. This cap contains a 28.5 mm rod with a groove in which the filter paper is located.

Cap B: Polypropylene cap. 10.5 mm external diameter, 13.1 mm high. Wall thickness: 1.2 mm

Filter paper: 5.0 x 25.0 mm, located in cap A rod.

Glass ampoule in tube B: 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.

$\geq 10^6$ *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 at 160 °C. Another D-value is estimated at 170 °C for the calculation of Z-value.

Z-value: 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 %, keep out of direct light.

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

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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.

Packing

50 units per box - 25 tubes A + 25 tubes B.

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

Labelling

On product's box: 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, ethylene oxide, vaporized hydrogen peroxide, formaldehyde or any other sterilization process other than dry heat.

Do not freeze.