

Infection Control Division | **Biological Indicators**

BT31 Spore ampoules

For dry heat sterilization processes



Usage

Monitoring dry heat sterilization processes. Compatible with extremely high temperatures generated during depyrogenation cycles and sterilization processes in ovens and dry heat tunnels.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016. ISO 11138-1:2017 and ISO 11138-4:2017.

Authorization

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

Classification

Class 1, according to risk (ANMAT).

Characteristics

Glass ampoule. 10.2 mm internal diameter. Wall thickness of 0.5 mm. Length: 58.0 mm.

Between 1.0×10^6 and 4.9×10^6 *Bacillus atrophaeus* ATCC® 9372 spores per ampoule.

Upon completion of the sterilization cycle, the content of the ampoule should be incubated in a suitable culture medium at 37 ± 2 °C.

Terragene S.A. suggests the use of Bionova® MC1030-2 Culture Medium or Bionova® MC1020-2 Culture Medium to final reading in 72 hours.

D-value: Not lower than 2.0 minutes at 160 °C.

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 in a dark place.

Transportation 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, applicable standards, storage conditions and manufacturer information.

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

Infection Control Division | **Biological Indicators**

BT31 Spore ampoules

For dry heat sterilization processes



Labeling

On the ampoule: Product code, process for intended use, bacterial strain, batch number, expiration date and trademark.

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

Possible target markets

Healthcare and Industry.

Other important information

It is advisable to incubate the content of Bionova® BT31 in Bionova® MC1030-2 Culture Medium or Bionova® MC1020-2 Culture Medium at 37 ± 2 °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 expose this product to steam, radiation or any sterilization process other than dry heat.