

Infection Control Division | Biological Indicators

## BT21 Self-Contained Spore Ampoules For steam sterilization processes of liquids



### Usage

Monitoring industrial steam sterilization processes of liquids between 121-135 °C.

### Applicable regulation

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

ISO 11138-1:2017, ISO 11138-3:2017 and ISO 11138-8:2021.

### Authorization

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

### Classification

Class 1, according to risk (ANMAT).

### Characteristics

Glass ampoule: 6.8 mm internal diameter. Wall thickness: 0.2-0.3 mm. Length: 40.0 mm.

Culture medium: 0.5 ml, purple color.

$\geq 10^6$  *Geobacillus stearothermophilus* ATCC®\* 7953 spores per ampoule.

Incubation conditions: 48 hours (maximum), between 55-62 °C.

Culture medium turns to yellow if sterilization process failure has occurred.

D-value: Not lower than 1.5 minutes at 121 °C. D-values at 132 °C and 135 °C are also informed.

Z-value: Not lower than 6 °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 = 2-8 °C (in refrigerator), RH = 30-80 %, keep out of direct light. Storage at room temperature (up to 25 °C) is possible for a period not longer than 15 days.

### 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.

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

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### Packing

200 units + 20 negative controls per box (negative controls are marked with a colored dot on one end).

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

### Labelling

On product's packing: Product code and description, bacterial strain and load, batch number, manufacture and expiration date, bar code and Data Matrix.

### Possible target markets

Healthcare and Industry.

### Other important information

It is advisable to incubate at 60 °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 ethylene oxide, hydrogen peroxide, dry heat, formaldehyde or any other sterilization process other than steam.

Do not freeze.