

Infection Control Division | **Biological Indicators**

BT24/6 Self-Contained spore ampoules.

For Steam sterilization processes of liquids.



Usage

Monitoring industrial Steam sterilization processes of liquids in small containers at low temperature between 110 °C – 121 °C.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016. ISO 11138-1:2017 and ISO 11138-3:2017; IRAM 37102-1:1999 and IRAM 37102-3:1999.

Authorization

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

Classification

Class 1, according to risk.

Characteristics

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

Culture medium 0.6 ml, **fuchsia/red** color.

10^6 *Bacillus subtilis* DSM 5230 ATCC 35021 spores per ampoule.

Incubation conditions: 48 hours (maximum), between 35 – 39 °C

Culture medium turns to **yellow** due to spore growth.

D-Value is calculated at 115 °C and at 121 °C.

Z-Value is informed.

Environmental conditions during manufacture

Refrigerated. 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.

Transport conditions

Storage conditions should be strictly followed.

Transport in closed reinforced boxes to avoid damage.

The transport of this product does not represent a risk for health.

Ampoules can remain at temperature below 25 °C for up to 2 hours during transportation.

If necessary, ampoules might be frozen for transportation. This process does not alter the viability and / or functionality of the product.

Shelf life

2 years.

Packing

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

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Packing information: product description, process for intended use, regulation, 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 datamatrix code.

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, Dry Heat, Radiation or any sterilization process other than Steam.