

BT24/4

Self-Contained spore ampoules.

For Steam sterilization processes of liquids.



Usage

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

Applicable Regulation

ISO 11138-1:2006 / ISO 11138-3:2006; IRAM 37102-1:1999 / IRAM 37102-3:1999.

Classification

Class 1, according to risk.

Authorization

Designed under Quality Management Systems ISO 9001:2008 and ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM-1614-1.

Characteristics

Glass ampoule (borosilicate type I). 7.0 mm internal diameter. Wall thickness of 0.2 – 0.3 mm. Length: 40.0 mm.

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

10^4 *Bacillus subtilis* DSM 5230 ATCC 35021 spores per ampoule. Confirmation readout within 48 hours (maximum). Culture medium changes to **yellow** when spores grow. Incubation at 37 °C.

D-Value_{STEAM}: calculated at 115 °C. Another D- Value is calculated at another temperature for Z-Value calculation.

Z-Value_{STEAM}: not lower than 6 °C.

Environmental conditions during manufacture

Refrigerated. Sterility conditions are necessary only during the filling and sealing process, carried out under laminar flow conditions.

Storage conditions

Store at 4-8 °C in refrigerator, RH 30-80 %, keep out of direct light.

Transportation conditions

Storage conditions should be strictly followed.

Transport in closed reinforced boxes to avoid damage. 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

24 months.

Packing

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

Information only on box's label.

Labelling

On product's box: Product code and description, presentation, batch number, expiration date and manufacturer information.

Possible target markets

Healthcare and Industry.

Other important information (optional)

It is advisable to incubate at 37 °C in BIONOVA INCUBATOR.

Read product's directions for use thoroughly before use.

Note: When necessary, limits of each product's parameters should be specified.

Description of identified and/or predictable risks which could represent a risk for the product

Do not store the product near sterilizing agents.

Store in refrigerator at 4 - 8 °C.

Do not expose to direct light for longer than 24 hours.

Do not expose this product to EO, Dry Heat, Radiation or any sterilization process other than Steam.

The positive biological indicator can be autoclaved at 121°C for at least 20 minutes, at 132 °C for at least 15 minutes in gravity displacement steam sterilization, or at 134 °C for at least 10 minutes in vacuum steam sterilizer.