

BT23/6

Self-Contained spore ampoules.

For Steam sterilization processes of liquids.



Violet = Sterile



Yellow = Non sterile

Usage

Monitoring industrial Steam sterilization processes of liquids at 121 °C – 134 °C.

Applicable Regulation

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

Classification

Class 1, according to risk.

Authorization

Designed under Quality Management System standards 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). 10.0 mm internal diameter. Wall thickness of 0.5 mm. Length: 58.0 mm.

Culture medium 2.0 ml, **violet** color.

10⁶ *G. stearothermophilus* ATCC 7953 spores per ampoule.

Confirmation readout within 48 hours (maximum). Culture medium changes to **yellow** when spores grow. Incubation at 60 °C.

D-Value _{STEAM}: not lower than 1.5 minutes at 121 °C. Another D-Value is calculated at 128 °C for the Z-Value calculation.

Z-Value _{STEAM}: not lower than 6 °C.

Environmental conditions during manufacture

Room temperature 15-30 °C, RH 30-80 %. Sterility conditions are necessary only during the inoculation process performed in laminar flow.

Storage conditions

Store at 4-8 °C in refrigerator, RH 30-80 %, keep out of direct light. Storage at room temperature (up to 25 °C) is possible for a period no longer than 15 days.

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 be stored at temperature below 25 °C for up to 15 days during transportation.

Shelf-life

24 months.

Packing

50 units + 5 negative controls per box.

Information on box's label.

Weight per box: 294,7 g

Labelling

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

On the ampoules: Product code, batch number, trade mark and bacterial strain data.

Possible target markets

Healthcare and Industry.

Other important information (optional)

It is advisable to incubate at 60 °C in a BIONOVA® IC 10/20 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.