

Infection Control Division | Biological Indicators

BT50 Spore strip biological indicator

For steam and formaldehyde sterilization processes



Usage

Monitoring 121-135 °C steam and formaldehyde sterilization processes.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016. ISO 11138-1:2017, ISO 11138-3:2017 and ISO 11138-5:2017.

Authorization

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

Classification

Class 1, according to risk (ANMAT).

Characteristics

25 mm x 70 mm non-absorbent material package. Brown code.

5 mm x 25 mm filter paper strip.

10⁶ *Geobacillus stearothermophilus* ATCC®* 7953 spores per strip.

Upon completion of the sterilization cycle, the spore strip should be tested in a suitable culture medium. Terragene S.A. suggests the use of Bionova® MC1020-2 culture medium.

Incubation conditions:

24 hours, between 55-62 °C for steam sterilization processes.

48 hours, between 55-62 °C for formaldehyde sterilization processes.

For conventional culture media like TSB, incubation for 7 days between 55-62 °C is recommended.

D-Value_{STEAM}: Not lower than 1.5 min. Conditions: 121 °C.

Z-Value_{STEAM}: Not lower than 6 °C.

D-Value_{FORM}: Not lower than 6.0 min. Conditions: 60 °C, 1 mol/l formaldehyde.

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 %.

Transport conditions

Storage conditions should be 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

100 units per aluminum foil bag.

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

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Labelling

On product's envelope: Product code and description, process for intended use, batch number, expiration date, bacterial strain and datamatrix code.

On product's packing: Product code and description, process for intended use, bacterial strain and load, batch number, manufacture and expiration date, presentation, regulation, storage conditions, manufacturer information, barcode and datamatrix code.

Possible target markets

Healthcare and Industry.

Other important information

It is advisable to incubate at 60 °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 radiation, hydrogen peroxide or any sterilization process other than steam and/or formaldehyde.