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Product Name

BTM60G/6 – Dual Spore Mini Strips Biological Indicator for Ethylene Oxide, Steam and Dry Heat sterilization processes, in single glassine packaging.

Usage

Monitoring Ethylene Oxide (EO), Steam and Dry Heat Sterilization Processes.

Applicable Regulation

EN ISO11138-1:2007, EN ISO11138-2:2009, EN ISO11138-3:2009 and EN ISO11138-4:2007; IRAM 37102-1:1999, IRAM 37102-2:1999 and IRAM 37102-3:1999.

Product Classification

Class 1, according to risk.

Authorization

Design under Quality Controls integrated systems EN ISO 9001:2008 and EN ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM-1614-1.

Product Characteristics

20 mm x 35 mm glassine package, Violet code.

2 mm x 10 mm filter paper mini strip.

10^6 *Geobacillus stearothermophilus* ATCC 7953 spores and 10^6 *Bacillus atrophaeus* ATCC 9372 spores per mini strip.

Upon completion of the sterilization cycle, the spore mini strip should be tested in a suitable culture medium at 37 °C or at 60 °C. We suggest the use of BIONOVA® MC1020 or MC1030 culture media to final reading in 48 hours at 37 °C for Ethylene Oxide and Dry Heat sterilization process control, or BIONOVA® MC20 or MC1020 culture media to final reading in 24 hours at 60 °C for Steam sterilization process control. For conventional culture media like TSB, incubation for 7 days is recommended.

D-Value_{STEAM}: Not lower than 1.5 minutes at 121 °C. Another D-Value is estimated at 134 °C for the calculation of Z-Value.

Z-Value_{STEAM}: Not lower than 6 °C.

D-Value_{EO}: Not lower than 2.5 minutes, conditions: 600 mg/l EO, 60 % RH, 54 °C.

D-Value_{DRY HEAT}: Not lower than 2.5 minutes at 160 °C. Another D-Value is estimated at 180 °C for the calculation on Z-Value.

Z-Value_{DRY HEAT}: Not lower than 20 °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

T = 10-30 °C, RH 30-80%, keep in a dark place.

Transportation 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

24 months.

Packing

100 units per box.

Information only on box's label.

Labelling

On product's box: product code and description, process for intended use, presentation, bacterial strain data, batch number and expiration date.

Possible target markets

Healthcare and Industry

Other important information (optional)

It is advisable to incubate at 60 °C or at 37 °C in BIONOVA® IC10/20 incubator.

Read product's directions for use thoroughly before use.

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



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

Do not store the product near sterilizing agents.

Do not expose this product to Radiation, H₂O₂ or any sterilization process other than EO, Steam and/or Dry Heat.

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

Note: Spore mini strips can be incubated in BIONOVA® MC20, MC1020 or MC1030 culture media or other culture medium made up of soybean casein and yeast extract.