



TERRAGENE



Product Name

BTM92G/6 – Spore Mini Strips Biological Indicator for plasma or vapor Hydrogen Peroxide sterilization processes, in single glassine packaging.

Usage

Monitoring plasma or vapor Hydrogen Peroxide Sterilization Processes.

Applicable Regulation

EN ISO11138-1:2007, IRAM 37102-1:1999.

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 non-absorptive material package. Blue code.

2 mm x 10 mm polyethylene fibers mini strip.

10^6 *Geobacillus stearothermophilus* ATCC 7953 spores per mini strip.

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

D-value: at 45 °C, 2 mg/l H₂O₂.

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 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.