



TERRAGENE



Product Name

BTM70G/6 –Spore Mini Strips Biological Indicator for Gamma Radiation sterilization processes, in single glassine packaging.

Usage

Monitoring Gamma Radiation Sterilization Processes.

Applicable Regulation

EN ISO 11138-1:2007; 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 glassine package. Fuchsia code.

2 mm x 10 mm filter paper mini strip.

10^6 *Bacillus pumilus* ATCC 27142 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. We suggest the use of BIONOVA® MC70 culture medium to final reading in 48 hours. For conventional culture media like TSB, is recommended incubation for 7 days at 37 °C.

D-Value: Calculated using Limited Holcomb-Spearman-Karber method.

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 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.

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 Steam, H₂O₂ or any sterilization process other than Gamma Radiation.

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 BIONOVA® MC70 culture medium or other culture medium made up of soybean casein and yeast extract.