

BTD70-4/6

Spore Discs Biological Indicator

For Gamma Radiation sterilization processes.



Usage

Monitoring Gamma Radiation Sterilization Processes. For industrial use only.

Applicable Regulation

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

Classification

Class 1, according to risk.

Authorization

Design under Quality Management Systems standards ISO 9001:2008 and ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-1.

Characteristics

1/4" (6.35 mm) diameter filter paper disc.

10^6 *Bacillus pumilus* ATCC 27142 spores per disc.

Upon completion of the sterilization cycle, the spore disc 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, incubation for 7 days at 37 °C is recommended.

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 envelope.

Packing information: operating instructions, classification according to regulation, manufacturer information and data on envelope 's label.

Weight per envelope: 14,0 g.

Labelling

On product's envelope: product code and description, process for intended use, operating instructions, presentation, batch number, expiration date and manufacturer information.

Possible target markets

Industry.

Other important information (optional)

It is advisable to incubate at 37 °C in 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 which could represent a risk for the product

Do not store the product near sterilizing agents.

Do not expose this product to EO, 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 discs can be incubated in Bionova® MC70 culture medium or other culture medium made up of soybean casein and yeast extract.