

BT93/6

Spore Coupons

For Plasma or Vaporized Hydrogen Peroxide sterilization processes



Usage

Monitoring Plasma or Vaporized Hydrogen Peroxide (H₂O₂) Sterilization Processes.

Applicable Regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN ISO 13485:2016.
ISO 11138-1:2017 and IRAM 37102-1:1999.

Classification

Class 1, according to risk.

Authorization

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

Characteristics

25 mm x 70 mm non-absorptive material package. Blue code.
Stainless steel coupon 34.0 mm x 7.0 mm x 0.8 mm.



10⁶ *Geobacillus stearothermophilus* ATCC 7953 spores per coupon.
Upon completion of the sterilization cycle, the spore coupon should be tested in a suitable culture medium. We suggest the use of Bionova® MC1020-2 culture medium.
Incubation conditions: 24 hours, between 55-62 °C.
For conventional culture media like TSB, incubation for 7 days between 55-62 °C is recommended.

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 strictly 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.

Labelling

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

On product's packing: product code and description, bacterial strain, process for intended use, bacterial load, batch number, manufacture date, expiration date, presentation, classification according to 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 directions for use thoroughly before use.

Precautions

Do not store the product near sterilizing agents.

Do not expose this product to Radiation, EO or any sterilization processes other than H₂O₂.