



TERRAGENE



Product Name

BT93/6 – Spore Coupon Biological Indicator for plasma or vapor Hydrogen Peroxide sterilization processes, in single glassine packaging.

Usage

Monitoring plasma or vapor Hydrogen Peroxide (H₂O₂) Sterilization Processes.

Applicable Regulation

EN ISO 11138-1:2007; IRAM 37102-1:1999.

Product Classification

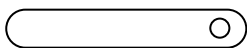
Class 1, according to risk.

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

25 mm x 70 mm non-absorptive material package. Blue code. Perforated 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 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, is recommended incubation for 7 days at 60 °C. D-value: at 45 °C, 2mg/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 = 15-30 °C, RH 35-60 %, 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.

Packing information: product code and description, process for intended use, classification according to regulation, manufacturer information and data on box 's label.

Information on product's package: product description, process for intended use, batch number, manufacture date and expiration date.

Labelling

On product's box: batch number, manufacture date 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.



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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, EO or any sterilization processes other than H₂O₂.

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 coupons can be incubated in BIONOVA® MC20 or MC1020 culture media or other culture medium made up of soybean casein and yeast extract.