



TERRAGENE



Product Name

BTC90-1/4 – Perforated Stainless Steel Coupon Biological indicator for plasma or vapor Hydrogen Peroxide sterilization.

Usage

Monitoring plasma or vapor Hydrogen Peroxide sterilization processes (H_2O_2).

Applicable Regulation

EN ISO 11138-1:2006 and IRAM 37102-1:1999.

Product Classification

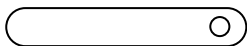
Class 1, according to risk.

Authorization

Design under Quality Controls integrated systems EN ISO 9001:2008 and EN ISO 13485:20012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM-1614-1.

Product Characteristics

Stainless steel perforated coupon of 34.0 mm x 7.0 mm x 0.8 mm.



10^4 *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 H_2O_2 .

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.

Packing information: Code, product description, process in which is used, presentation, classification according to regulation, batch number, production date, expiration date and manufacturer information.

Labelling

On the product's box: batch number, production 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 which could represent a risk for the product

Do not store the product near sterilizing agents.

Do not expose this product to EO, Dry heat, Radiation or any sterilization process other than Hydrogen Peroxide.

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 sterilizer, or at 134 °C for at least 10 minutes in vacuum steam sterilizer.

Note: The product can be incubated in BIONOVA® MC20 or MC1020 culture media or in a culture medium made up of soybean casein and yeast extract.