

Infection Control Division | Biological Indicators

BT91 Self-Contained Biological Indicator

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/ EN ISO 13485:2016.
ISO 11138-1:2017.

Authorization

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

Classification

Class 1, according to risk (ANMAT).

Characteristics

Polypropylene tube: 45.2 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.

Polypropylene cap: 13.0 mm high x 10.9 mm external diameter. Wall thickness: 0.7 mm.

Cap filter: Polyethylene fibers, 17.0 mm diameter, 64.0 g/m².

Glass ampoule: 35.0-40.0 mm high. External diameter: 6.8 mm. Wall

thickness: 0.2-0.3 mm.

Culture medium: 0.5-0.7 ml, purple color.

10⁶ *Geobacillus stearothermophilus* ATCC®* 7953 spores per vial.

Upon completion of sterilization process, incubate the indicator for a maximum of 24 hours at temperature between 55-62 °C.

Positive growth results (failure in the sterilization process): culture medium turns to yellow after incubation between 55-62 °C for 24 hours (maximum).

D-Value at 50 °C, 2.0 mg/l H₂O₂.

Environmental conditions during manufacture

T = 15-30 °C, RH = 30-80 %. Sterility conditions are only necessary during the inoculation and manufacturing process, which is performed in laminar flow.

Storage conditions

T = 10-30 °C, RH 30-80 %, keep in a dark place in its original box.

*ATCC® is a registered trademark of American Type Culture Collection.

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Transport conditions

It is recommended to store it away from sunlight and at temperature between 10 – 30 °C.

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 box.

Box's information: Product code and description, process for intended use, regulatory and standards information, bacterial strain, storage conditions and manufacturer information.

Labelling

On product's packing: Product code, presentation, batch number, bacterial load, manufacture and expiration date, barcode and Data Matrix.

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 instructions for use thoroughly before use.

Precautions

Do not store near sterilizing agents.

Do not use to control ethylene oxide, dry heat, radiation or any sterilization process other than hydrogen peroxide.