Terragene®

Product Description

Rev. 12 | Date: 08-2021

Infection Control Division | **Biological Indicators**

BT95 Self-Contained Biological Indicator

Rapid readout fluorescence system

Usage

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

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.

Authorization

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

Classification

Class 1, according to risk (ANMAT).

FDA 510(k)

K191021

Characteristics

Polypropylene tube: 50.4 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.
Polypropylene cap: 16.4 mm high x 10.7 mm external diameter. Wall thickness: 0.9 mm.
Cap filter: polyethylene fibers, 17.0 mm diameter.
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.
Polypropylene microfibers on spore carrier: 17 mm of diameter.
Spore carrier: polyethylene fibers. 17 mm of diameter.
≥ 10^6 *Geobacillus stearothermophilus* ATCC 7953 spores per vial.
Final fluorescence reading is performed after 2-hour incubation at 60 °C (sensitivity ≥ 97 %).
An optional visual pH color change confirmation could be performed after 48 hours of incubation. If sterilization process has not been successful, culture medium will change to a greenish color first, and then to yellow during incubation at 60 °C, thus showing the presence of living spores. If sterilization process is successful culture medium will remain purple after the incubation process.
7-day readout is optional and not intended to be routinely performed; it is an initial validation of the 2-hour reading. Fluorescence results may be compared to the 7-day visual reading.
NOTE: If 7-day readout is performed, a humidified environment will be required to prevent medium from drying out.

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.

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Storage conditions

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

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

50 units per box.
Packing information: product code and description, process for intended use, presentation, regulation, bacterial strain, storage conditions, manufacturer information and data on pack´s label.

Labelling

On product: 17.0 mm x 33.0 mm polypropylene label. 1.5 mm chemical indicator line, printed with H_2O_2 reactive ink (color change to green). Graph showing final fluorescence reading time, product code, batch number, expiration date, process for intended use and name of organism printed in black.
On product's packing: product code and description, batch number, bacterial population, manufacture and expiration date, bar code and datamatrix code.
NOTE: manufacture date is calculated by subtracting 24 months to the expiration date.

Possible target markets

Healthcare and Industry.

Other important information

It is advisable to incubate at 60 ºC in Bionova® IC10/20FR, IC10/20FRLCD or MiniBio Auto-Reader incubators.
Read product's instructions for use thoroughly before use.

Precautions

Do not store the product near sterilizing agents.
Do not expose this product to Ethylene Oxide, Dry Heat, Radiation or any sterilization process other than Hydrogen Peroxide.