

Infection Control Division | Biological Indicators

BT40 Spore strip biological indicator

For ethylene oxide and dry heat sterilization processes



Usage

Monitoring ethylene oxide (EO) and dry heat sterilization processes.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016 / EN ISO 13485:2016.

ISO 11138-1:2017, ISO 11138-2:2017 and ISO 11138-4:2017.

Authorization

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

Classification

Class 1, according to risk (ANMAT).

Characteristics

Envelope: 25 mm x 70 mm non-absorbent material package, green edges.

Strip: 5 mm x 25 mm filter paper strip.

10^6 *Bacillus atrophaeus* ATCC® 9372 spores per strip.

Upon completion of the sterilization cycle, the spore strip should be tested in a suitable culture medium at 37 °C. Terragene S.A. recommends the use of Bionova® MC1030-2 or Bionova® MC1020-2 culture media for final reading in 48 hours. For conventional culture mediums, such as TSB, incubation for 7 days at 37 °C is recommended.

D-Value_{DRY}: Not lower than 2.0 min. Conditions: T = 160 °C.

Z-Value_{DRY}: Not lower than 20 °C.

D-Value_{EO}: Not lower than 2.0 min. Conditions: 600 mg/l EO (100 %), RH = 60 %, T = 54 °C.

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 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.

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

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Packing

100 units per aluminum foil bag.

Labelling

On each individual envelope: Product code and description, process for intended use, batch number, expiration date, bacterial strain and Data Matrix.

On bag's label: Product code and description, process for intended use, bacterial strain and load, batch number, manufacture and expiration date, presentation, regulation, storage conditions, manufacturer information, barcode and Data Matrix.

Possible target markets

Healthcare and Industry.

Other important information

It is advisable to incubate at 37 °C in Bionova® IC10/20 incubator. Read product's Instructions for use thoroughly before use.

Precautions

Do not store the product near sterilizing agents. Do not expose this product to radiation, hydrogen peroxide or any sterilization process other than EO and/or dry heat.