

Infection Control Division | Biological Indicators

BT20 Self-Contained Biological Indicator For steam sterilization processes



Usage

United States

Terragene® Bionova® BT20 Biological Indicator is a Self-Contained Biological Indicator (SCBI) intended for routine monitoring of the efficacy of the following steam sterilization processes:

- Gravity-displacement Steam Sterilization Cycles
 - 121 °C, 30 minutes
 - 132 °C, 25 minutes
 - 132 °C, 15 minutes
 - 132 °C, 10 minutes
 - 134/135 °C, 10 minutes
- Vacuum-assisted Steam Sterilization Cycles
 - 121 °C, 20 minutes
 - 132 °C, 4 minutes
 - 134/135 °C, 3 minutes

Terragene® Bionova® BT20 provides a final result after a 24-hour incubation at 60 ± 2 °C.

Outside the United States

Terragene® Bionova® BT20 Biological Indicators have been designed for quick and easy routine monitoring of gravity-displacement and vacuum-assisted steam sterilization cycles at 121-135 °C. Terragene® Bionova® BT20 provides a final result after a 24-hour incubation at 60 ± 2 °C.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016 / EN ISO 13485:2016. ISO 11138-1:2017, ISO 11138-3:2017 and ISO 11138-8:2021.

Authorization

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

Classification

Class 1, according to risk (ANMAT).

FDA 510(k)

K251122.

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: medical grade paper, 17.0 mm diameter.

Glass ampoule: 35.0 - 40.0 mm high. External diameter: 6.5 mm. Wall thickness: 0.2 - 0.3 mm.

Culture medium 0.5 - 0.7 ml, purple color.

Spore carrier: filter paper, 7.0 mm diameter.

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10^6 *Geobacillus stearothermophilus* ATCC®* 7953 spores per vial.
Upon completion of the sterilization cycle, incubate the indicator for a maximum of 24 hours at a temperature between 58-62°C. Positive growth results (failure in the sterilization process): culture medium turns to yellow after incubation between 58-62°C for 24 hours (maximum).

D-value: not lower than 1.5 minutes at 121 °C. Not lower than 10 seconds at 132°C. Not lower than 8 seconds at 135°C.

Z-value: not lower than 10°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 %, keep in a dark place in its original box.

Transport conditions

It is recommended to store it away from light and at a 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

30 or 100 units per box.

10 units per bag.

Labelling

On product's box and label: product code and description, intended use, standards and regulations data, bacterial strain and load, storage conditions, manufacturer information, batch number, manufacture and expiration date, presentation, bar code and Data Matrix.

On product's bag: product code and description, intended use, standards and regulations data, bacterial strain and load, storage conditions, manufacturer information, batch number, manufacture and expiration date, presentation, bar code and Data Matrix.

Possible target markets

Healthcare and Industry.

Other important information

Read product's Instructions for Use thoroughly before use.

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

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Precautions

Do not store the product near sterilizing agents.
Do not use this product to control hydrogen peroxide, ethylene oxide, dry heat, formaldehyde or other sterilization processes.
Do not freeze.