

Infection Control Division | **Biological Indicators**

## BT98 Self-Contained Biological Indicator

### Hyper rapid readout fluorescence system



#### Usage

##### United States

Monitoring the efficacy of Plasma or Vaporized Hydrogen Peroxide sterilization processes in the following systems:

- Sterrad® 1 00S Sterilization System.
- Sterrad® NX Sterilization System (Standard and Advanced Cycles).
- Sterrad® NX with ALLClear® Technology Sterilization System (Standard and Advanced Cycles).
- Sterrad® IOONX Sterilization System (Standard, Flex, Express and Duo Cycles).
- Sterrad® IOONX with ALLClear® Technology Sterilization System (Standard, Flex, Express and Duo Cycles).
- V-Pro® S2 Low Temperature Sterilization System (Fast, Non Lumen, Lumen and Flexible Cycles).
- V-Pro® maX 2 Low Temperature Sterilization System (Fast Non Lumen, Non Lumen, Lumen and Flexible Cycles).

##### Outside the United States

Monitoring plasma or vaporized Hydrogen Peroxide sterilization processes (H<sub>2</sub>O<sub>2</sub>).

#### 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)

K221641.

#### 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, 64.5 g/m<sup>2</sup>.

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, 60 g/m<sup>2</sup>.

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

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Spore carrier: polyethylene fibers. 17 mm of diameter, 64.5 g/m<sup>2</sup>.  
≥ 10<sup>6</sup> *Geobacillus stearothermophilus* ATCC®\* 7953 spores per vial.  
Final fluorescence reading is performed after 5 minute-incubation at 60 °C (sensitivity ≥ 97 %).

An optional visual confirmation could be made after 5 days of incubation. Color change of the culture medium is developed by pH variation when microorganisms grow. If sterilization process has not been successful, culture medium will change from purple 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.

NOTE: if 5-day readout is performed, a humidified environment will be required to avoid medium to dry out.

7-day readout is optional and not intended to be routinely performed; it is an initial validation of the 5 minute-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 avoid medium to dry 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.

#### Storage conditions

T = 10-30 °C, RH = 30-80 %, keep in a dark place in its original box. It is recommended to respect the storage conditions during transport.

#### Transport conditions

It is recommended to store it away from sunlight 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.

Acceptable excursions during transport are as follows:

T = 2-10 °C and T = 30-37 °C for no longer than seven days. No restrictions for relative humidity.

#### Shelf life

2 years.

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#### 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<sub>2</sub>O<sub>2</sub> 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.

#### Possible target markets

Healthcare and Industry.

#### Other important information

It is advisable to incubate at 60 °C in Bionova® Hyper Rapid 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.