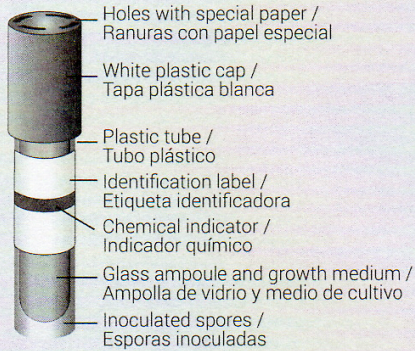
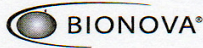


# BT91 Biological Indicator

Rev. 19 / 12.2020



Producto Autorizado por ANMAT PM 1614-1

## Quality certification Certificado de calidad Bionova® BT91

VH202

Plasma or Vaporized Hydrogen Peroxide sterilization  
/ Esterilización por Plasma o Vapor de Peróxido de Hidrógeno  
*Geobacillus stearothermophilus* ATCC 7953

LOT A30342

2023-08

2025-08

Population / Población  $1.6 \times 10^6$  CFU/UFC

D - value / Valor D 66 sec./seg.  
(2.0 mg/L  $\text{VH}_2\text{O}_2$ , 50°C)

Survival time / Tiempo de sobrevivencia 4.7 min.  
Survival time =  $(\log_{10} \text{ labeled population} - 2) \times \text{labeled D-value}$

Kill time / Tiempo de muerte 11.3 min.  
Kill time =  $(\log_{10} \text{ labeled population} + 4) \times \text{labeled D-value}$

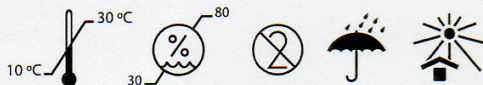
Parameters determined at time of manufacture according to ISO 11138-1: 2017 and IRAM 37102-1: 1999 standards. The shown values are reproducible only under the same conditions under which they were determined.

Parámetros determinados al momento de la fabricación según normas ISO 11138-1: 2017 e IRAM 37102-1: 1999. Los valores presentados son reproducibles solo bajo las mismas condiciones en las cuales fueron determinados.

ISO and USP Compliant  
ATCC is a registered trademark of American Type Culture Collection

Lic. Adrián J. Rovetto  
Director Técnico  
Technical Director

Uso exclusivo para profesionales e Instituciones Sanitarias.



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## Biological Indicator

For Plasma or Vaporized Hydrogen Peroxide sterilization

### Composition

Each tube contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores deposited on the inner surface of the plastic tube base. It also has a growth indicator media of purple color contained in the glass ampoule.

### Product description

Bionova® BT91 Biological Indicator is specifically designed for the monitoring of Plasma or Vaporized Hydrogen Peroxide sterilization processes. If sterilization process was not successful, the indicator media will change from purple to yellow after incubation between 55-62 °C, thus indicating the presence of live *Geobacillus stearothermophilus* spores. If the sterilization process was effective, the indicator media will remain purple after incubation. The final readout should be made after 24 hours of incubation between 55-62 °C.

### Precautions

Do not use Bionova® BT91 Biological Indicator for monitoring Steam sterilization cycle, Ethylene Oxide, Dry Heat, Formaldehyde or other sterilization processes.

Do not re-use the biological indicators.

Do not use the sterilizer until the biological indicator test results are negative.

### Storage

Store in a dark place under the next conditions: Temperatures between 10-30 °C, relative humidity 30-80 %. Do not freeze. Do not store biological indicators near sterilizing agents or other chemical products.

### Instructions for use

1. Identify the Bionova® BT91 Indicator by writing the sterilizer number (in case of having more than one sterilizer), load number, and processing date on the indicator label.
2. Pack the biological indicator along with materials to be sterilized in an appropriated package according to recommended sterilization practices. Place this package in those areas which a priori you consider most inaccessible for sterilizing agent.
3. Sterilize as usual.
4. After the sterilization process has finished, remove the biological indicator from sterilization package for incubation.
5. Check the chemical indicator on the label of biological indicator. A color change to green confirms that the biological indicator has been exposed to Hydrogen Peroxide. **IMPORTANT:** This color change does not indicate

that the process was sufficient to achieve sterility. If the chemical indicator is unchanged, check the sterilization process.

6. Crush the glass ampoule contained in the biological indicator and incubate between 55-62 °C. **IMPORTANT:** Use a non-sterilized biological indicator as a positive control at least once per day, when a sterilization cycle is run. The positive control ensures that correct incubation conditions were met. Both the positive control indicator and the processed indicator should belong to the same batch.

7. Incubate the processed biological indicator and the indicator used a positive control for a maximum of 24 hours between 55-62 °C.

A color change from purple to yellow of the growth indicator medium means that sterilization process failure has occurred. If after 24 hours there is no color change in the processed indicators, a final negative result is made (the sterilization process was effective). The positive control indicator should show a purple to yellow color change for the result to be valid. **NOTE:** To extend the incubation time to more than 24 hours, we recommend using a humidified environment to prevent the complete evaporation of the culture medium contained in the indicator. Record the results and discard immediately as it is shown below.

### Disposal

Discard biological indicators after use according to your country's healthcare and safety regulations. The positive biological indicators can be autoclaved in a gravity air displacement steam sterilizer at 121 °C for 30 minutes, 132 °C for 15 minutes or 134 °C for 10 minutes; or in a dynamic air removal steam sterilizer at 132 °C for 4 minutes or 135 °C for 3 minutes.