

# BT20

## Self-Contained Biological Indicator.

*For Steam sterilization processes.*



### Usage

Monitoring vacuum-assisted Steam Sterilization processes at 121 °C – 134 °C and gravity air- displacement Steam Sterilization processes at 121 °C – 134 °C.

### Applicable Regulation

ISO 11138-1:2006 and ISO 11138-3:2006; IRAM 37102-1:1999 and IRAM 37102-3:1999.

### Classification

Class 1, according to risk.

### Authorization

Designed under Quality Management System standards ISO 13485:2003/NS-EN ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-1.

### Characteristics

Polypropylene random copolymer tube: 45.0 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.

Polypropylene cap: 10.5 mm diameter, 13.0 mm high. Wall thickness: 1.0 mm.

Glass ampoule: 35.0 – 38.0 mm high. External diameter: 6.5 mm. Wall thickness: 0.2 – 0.3 mm.

Culture medium: 0.5 – 0.7 ml, **purple** color.

Cap filter: medical grade paper, 60 g/m<sup>2</sup>, 16.0 mm diameter.

Filter Paper: 8.0 mm diameter, 160 g/m<sup>2</sup>.

10<sup>5</sup> or 10<sup>6</sup> *Geobacillus stearothermophilus* ATCC 7953 spores per vial.

Positive growth results (failure in the sterilization process): culture medium turns to **yellow**, incubation at 60 °C for 24 hours (maximum).

D-Value: Not lower than 1.5 minutes at 121 °C.

Z-Value: Not lower than 6 °C.

### Environmental conditions during manufacture

Room temperature 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.

### Transportation conditions

Storage conditions should be strictly followed.

Products should be transported in closed and reinforced boxes in order to avoid damages. Product transportation does not represent any risk for human health.

### Shelf-life

24 months.

### **Packing**

30 units or 100 units per box.

Packing information: product code and description, process for intended use, presentation, classification according to regulation, bacterial strain, manufacturer information and data on box's label. Note: manufacture date is calculated by subtracting 24 months to the expiration date.

Weight per box(x100): 227,3 g.

Weight per box(x30): 80,6 g.

### **Labelling**

On product: 17.0 mm x 33.0 mm polypropylene label. Printed in black. 1.5 mm chemical indicator line, printed with Steam reactive ink (Color change to brown). Product code and batch number, process for intended use and bacterial strain.

On product's box: product code, batch number, bacterial load and manufacture and expiration date.

### **Possible target markets**

Healthcare and Industry.

### **Other important information (optional)**

It is advisable to incubate at 60 °C in BIONOVA® IC10/20 incubator. Read product's directions for use thoroughly before use.

**Note:** When necessary, limits of each product's parameters should be specified.

### **Description of identified and/or predictable risks which could represent a risk for the product**

Do not store the product near sterilizing agents.

Do not expose this product to EO, Dry Heat, Radiation or any sterilization process other than Steam.

The positive biological indicator can be autoclaved at 121 °C for at least 20 minutes, at 132 °C for at least 15 minutes in gravity displacement steam sterilization, or at 134 °C for at least 10 minutes in vacuum steam sterilizer.