

# BTD50-8/5

## Spore Discs Biological Indicator

*For Steam sterilization processes*



### Usage

Monitoring Steam Sterilization Processes. For industrial use only.

### 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

Design under Quality Management Systems standards ISO 9001:2008 and ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-1.

### Characteristics

1/8" (3.18 mm) diameter filter paper disc.

$10^5$  *Geobacillus stearothermophilus* ATCC 7953 spores per disc.

Upon completion of the sterilization cycle, the spore disc should be tested in a suitable culture medium at 60 °C. We suggest the use of Bionova® MC20 or MC1020 culture media to final reading in 24 hours. For conventional culture media like TSB, incubation for 7 days at 60 °C is recommended.

D-Value<sub>STEAM</sub>: not lower than 1.5 minutes at 121°C.

Another D-value is estimated at 134 °C for the calculation of Z-Value

Z-Value<sub>STEAM</sub>: 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**

100 units per envelope.

Packing information: operating instructions, classification according to regulation, manufacturer information and data on envelope 's label.

Weight per envelope: 14,0 g.

**Labelling**

On product's envelope: product code and description, process for intended use, operating instructions, presentation, batch number, expiration date and manufacturer information.

**Possible target markets**

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 radiation, H<sub>2</sub>O<sub>2</sub> 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.

Note: Spore discs can be incubated in Bionova® MC20 or MC1020 culture media or other culture medium made up of soybean casein and yeast extract.