



TERRAGENE



### Product name

**BT20S/6** – Spore suspension for direct inoculation of products or preparation of customized biological indicators for monitoring Steam, Hydrogen Peroxide and Formaldehyde Sterilization Processes.

### Use

For monitoring Steam, Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>) and Formaldehyde Sterilization Processes.

### Applicable regulations

EN ISO 11138-1:2007 and EN ISO 11138-3:2009, EN ISO 11138-5:2007; IRAM 37102-1:1999 and IRAM 37102-3:1999.

### Classification

Class 1, according to risk.

### Authorization

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

### Product characteristics

Glass bottle: 18 mm diameter, 0.3 mm thick wall, 60.7 mm high.  
 Plastic cap: 16 mm external diameter, 9.4 mm high.  
*Geobacillus stearothermophilus* ATCC 7953 spores.  
 Population: 10<sup>5</sup> spores/0.1 ml. Prepared in 40% ethanol.  
 D-Value<sub>STEAM</sub> is provided. Conditions: 121 °C. Another D Value is calculated at another temperature for Z value calculation.  
 Z Value<sub>STEAM</sub> is provided.  
 D-Value<sub>FORM</sub> is provided. Conditions: 60 °C for steam-formaldehyde.  
 D-Value<sub>H2O2</sub> is provided. Conditions: 2 mg/l H<sub>2</sub>O<sub>2</sub>, 45 °C.

Upon completion of the sterilization cycle, the inoculated product should be tested in a suitable culture medium at 60 °C. We suggest the use of culture media BIONOVA® MC20 or MC1020 to final reading in 24 hours for Steam/H<sub>2</sub>O<sub>2</sub> sterilization and 48 hours for Formaldehyde sterilization. For conventional culture media like TSB, incubation for 7 days at 60 °C is recommended.

### Environmental conditions during manufacture

Refrigeration during inoculation. Sterility conditions are necessary only during the filling and sealing process, carried out under laminar flow conditions.

### Storage conditions

For short-term use, store at 2–8 °C in refrigerator. Freeze to store for long periods (-10 to -25 °C). RH: 35-60%. Keep out of direct light.

### Transportation conditions

Storage conditions should be strictly followed. Transport in closed reinforced boxes to avoid damage. This product does not represent a risk for health. Bottles can be stored at temperature below 30 °C for up to 15 days during transportation.

### Shelf life

24 months.

### Packing

1 bottle with 10 ml of spore suspension within a plastic bag.

### Labelling

On the bottle: Product code and description, presentation and spore concentration, directions for use, batch number, manufacture and expiration date and manufacturer information.

### Possible target markets

Healthcare and Industry.

### Other important information (optional)

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

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



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**Description of identified and/or predictable risks and situations 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, H<sub>2</sub>O<sub>2</sub> and/or Formaldehyde.

The positive biological indicator can be sterilized in gravity air displacement steam sterilizers at 121 °C for at least 20 minutes or at 132 °C for at least 15 minutes, or at 134 °C for at least 10 minutes in vacuum-assisted steam sterilizers.

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