BIONOVA®

Product name

BT10S/7 – Spore suspension for direct inoculation of products or preparation of customized biological indicators for monitoring Ethylene Oxide and Dry Heat Sterilization Processes.

Use

For monitoring Ethylene Oxide (EO) and Dry Heat Sterilization Processes.

Applicable regulations

EN ISO 11138-1:2007 and EN ISO 11138-2:2009, EN ISO 11138-4:2007; IRAM 37102-1:1999 and IRAM 37102-2:1999.

Classification

Class 1, according to risk.

Authorization

Designed under Quality Systems ISO 9001:2008 and 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.
Bacillus atrophaeus ATCC 9372 spores.
Population: 10^6 spores/0.1 ml. Prepared in 40% ethanol.
Parameters specified:
D-Value$_{EO}$ is provided. Conditions: 600 mg/l EO, 60% RH, 54 ºC.
D-Value$_{DRY}$ is provided. Calculated at 160 ºC. Another D-value is estimated at 170 ºC for the calculation of Z-Value$_{DRY}$.
Z-Value$_{DRY}$ is provided.

Upon completion of the sterilization cycle, the inoculated product should be tested in a suitable culture medium at 37 ºC. We suggest the use of culture media BIONOVA® MC1020 or MC1030 to final reading in 48 hours. For conventional culture media like TSB, incubation for 7 days at 37 ºC 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 ºC in refrigerator. Freeze to store for long periods (-10 to -25 ºC). 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 ºC 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 37 ºC 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.

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 Steam, H_2O_2, Radiation or any sterilization process other than EO and/or Dry Heat.

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

Note: Spores can be incubated in culture media BIONOVA® MC1030 or MC1020 culture media or other culture medium made up of soybean casein and yeast extract.