

BT20

Self-Contained Biological Indicator.

For Steam sterilization processes.



Usage

Monitoring vacuum-assisted Steam Sterilization processes at 121 °C – 135 °C and gravity air – displacement Steam Sterilization processes at 121 °C – 135 °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: 45.2 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.

Polypropylene cap: 10.6 mm diameter, 13.0 mm high. Wall thickness: 0.9 mm.

Glass ampoule: 35.0 - 40.0 mm high. External diameter: 6.8 mm. Wall thickness: 0.2 – 0.3 mm.

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

Cap filter: medical grade paper, 60 g/m², 17.0 mm diameter.

Filter Paper: 7.0 mm diameter, 160 g/m².

10⁵ or 10⁶ *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. Another D-value is informed at 135°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.