



## **STERILAMP®**

### **SOLUTION STERILIZATION BIOLOGICAL INDICATORS**

**7953<sup>(1)</sup>** *G. stearothermophilus*; **35021** *B. subtilis* “5230”

- SterilAmp is a self-contained unit for monitoring the steam sterilization of liquids. A 26 mm sealed glass ampoule contains spores of *Geobacillus stearothermophilus* or *Bacillus subtilis* “5230” suspended in a specially formulated culture medium.
- Ampoules containing *Geobacillus stearothermophilus* should be sterilized at a temperature of 121°C and ampoules with spores of *Bacillus subtilis* “5230” are suitable for the temperature range of 105-116°C.

#### **Instructions for Use:**

1. Remove SterilAmp from the refrigerator and allow to stabilize at room temperature, approximately 30 minutes.
2. Place SterilAmp inside a container of liquid to be sterilized. Leave one sample aside as a positive control.
3. Assure the liquid container with the SterilAmp biological indicator is the same size and contains the same volume of liquid as the product containers being sterilized. NOTE: Generally, a minimum of 10 units are placed in each load.
4. Following exposure, remove the container with the SterilAmp biological indicator and place into an incubator and incubate samples for 48 hours.
  - a) *Geobacillus stearothermophilus* 55-60°C
  - b) *Bacillus subtilis* “5230” 35-39°C
5. If the spores survive the sterilization cycle, the culture medium will turn to yellow (positive). If the spores have been killed, the culture medium will remain the original color (purple - *G. stearothermophilus*; red - *B. subtilis* “5230”). NOTE: It is best to read results approximately every 12 to 24 hours. All positive (yellow) samples should be recorded and disposed of immediately. All yellow samples should be autoclaved prior to disposal.
6. Record test results.
7. Autoclave all positive samples prior to disposal.

<sup>(1)</sup> Culture is traceable to a recognized culture collection identified in USP and ISO 11138

**SterilAmp Advantages:**

- No special laboratory equipment is necessary to culture SterilAmp
- Fast read-out time of 48 hours
- Dramatic color change for positive cultures
- Small ampoule which can be placed inside vials or ampoules which contain small volumes of liquid product
- Sealed ampoules protect the manufacturing environment from spore contamination.
- Negative controls are included with each box of product.

**Certification:**

SterilAmp biological indicators are certified for population, D-value, Z-value, F<sub>0</sub> value, and performance. SterilAmp is manufactured in compliance with USP and ISO 11138.

**SterilAmp Biological Indicators are available as follows:**

	Units per box	Cat. No.
SterilAmp <i>G. stearothermophilus</i> 10 <sup>5</sup>	100	SA/5
SterilAmp <i>G. stearothermophilus</i> 10 <sup>6</sup>	100	SA/6
SterilAmp <i>B. subtilis</i> “5230” 10 <sup>6</sup>	100	SA/6

**Storage:** Refrigerate 2-8°C. Protect from light.

**Expiration:** 18 months from date of manufacture

Rev. 3  
Date: 10/31/06  
SGM Part #: 7813