



FOR INDUSTRIAL USE ONLY
CERTIFICATE OF ANALYSIS

SGM BIOTECH, INC.
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Reorder No: SA/

Geobacillus stearothermophilus 7953⁽¹⁾

Biological Indicator for: Steam Sterilization of solutions at 121°C.

Culture: 55 – 60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Purity: No evidence of contaminants using standard plate count techniques.

Lot No: SA-000 Manufacture Date: YEAR MONTH DAY

Expiration: 18 months from Manufacture Date.

Heat Shocked Population: 0.0 x 10 Spores / Unit

Assayed Resistance:	D-Value	Survival	Kill	
Steam 121°C	0.0 ⁽²⁾	00.0 ⁽³⁾	00.0 ⁽³⁾	min
F ₀		00.0 ⁽⁴⁾	00.0 ⁽⁴⁾	min
Z-value:	00.00°C			

D-value reproducible only when exposed in an AAMI BIER vessel and cultured under the exact conditions used to obtain results reported here. MPN method used.

Units are manufactured in compliance with SGM Biotech's quality standards, USP, and ISO 11138 guidelines and all appropriate subsections.

⁽¹⁾Culture is traceable to a recognized culture collection identified in USP and ISO 11138.
⁽²⁾D-value calculated using the Limited-Holcomb-Spearman-Karber method.
⁽³⁾Survival/Kill values are calculated according to a formula in USP and ISO 11138. SGM uses a D-value rounded to four decimal places in this calculation.
⁽⁴⁾Empirically derived data.

Certified By: _____

Complete Quality Control testing results available upon request.



Biological Indicators for Monitoring Steam Sterilization of Liquids

INSTRUCTIONS

Sterilization:

- Place **SterilAmp® II** inside representative liquid containers to be sterilized. Package or seal as usual. AAMI recommends a minimum of 10 BIs per cycle.
- Locate test samples in areas of the load considered most difficult to sterilize or in convenient areas that have been validated. Identify test samples as to location in sterilizer.
- After sterilizing, send **SterilAmp II** and products to test laboratory along with at least one non-sterilized **SterilAmp II** marked POSITIVE CONTROL.

Test Laboratory:

- All **SterilAmp II** are fully self-contained BIs which do not require subculture.
- Procedure:
 - SterilAmp II** may be left in the sterilized container or transferred to a rack or container which allows visual observation during incubation.
 - Incubate **SterilAmp II** for 48 hours at 55-60°C.
 - The 48 hour incubation meets the criteria established in the FDA protocol for validation of reduced incubation time (RIT).
 - Observe daily for growth.

Yellow = growth = non-sterile
Purple = no growth = sterile

SterilAmp II should show "no growth" if sterilization has been achieved.

If color change to yellow occurs in **SterilAmp II** cultures, it indicates that the spores have survived the sterilization process and are non-sterile.

Controls:

- Positive:** At least one positive control should be included in each test series. Incubate a non-sterilized **SterilAmp II** with test series. Color change from purple to yellow indicates that the medium possesses suitable growth promoting qualities and that the **SterilAmp II** contains viable spores. If positive control does not grow, do not use the units from that package. Contact SGM Biotech, Inc.

Storage and Disposal:

- Refrigerate at 2 – 8°C. Protect from light.
- Incinerate or autoclave at 121°C for not less than 30 minutes.
- SterilAmp II** biological indicators have an 18 month shelf life which is clearly designated on each package. Rotate your stock accordingly.

NOTE: Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.