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FOR INDUSTRIAL USE ONLY

CERTIFICATE OF ANALYSIS

Reorder No: SASU/6

Bacillus subtilis "5230" 35021⁽¹⁾

Biological Indicator for: Low Temperature Steam Sterilization of Solutions.

Culture: 35-39°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

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

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

Expiration: 15 months from Manufacture Date.

Heat Shocked Population: 0.0 x 10⁶ Spores / Unit

Assayed Resistance:	D-Value ⁽²⁾	Survival	Kill	
Steam (110°C)	0.0	00.0 ⁽³⁾	00.0 ⁽³⁾	min
Steam (115°C)	0.0	00.0 ⁽³⁾	00.0 ⁽³⁾	min
Steam (121°C)	0.0	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.

⁽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/F₀ data.

Certified By: _____



Biological Indicators for Monitoring Low Temperature Steam Sterilization

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 three days at 35-39° C.
 - Observe daily for growth.

Yellow = growth = non-sterile
 Red = 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 red 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 box. 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.