

CERTIFICATE OF ANALYSIS

Reorder No.: Bacillus subtilis '5230' 35021⁽¹⁾ Biological Indicator for: Low Temperature Steam Sterilization Culture: Soybean casein digest broth. Purity: No evidence of contaminants using standard plate count techniques. Lot No.: B5230-000 Manufacture Date: YEAR MONTH DAY Expiration Date: 24 months from Manufacture Date Heat Shocked Population: $0.0 \ge 10^{\circ}$ Spores / Unit 1" x ¼" (25 mm x 6 mm) Carrier Size: Assaved Resistance: D-Value⁽²⁾ Survival Kill (3) (3)Steam (115°C) (4) (4) Steam (118°C) (4)(4)Steam (121°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 Mesa Laboratories' 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. A D-value rounded to four decimal places is used in this calculation.

⁽⁴⁾ Empirically derived data.

Certified By:

Z-value:

°C

Quality Representative

Complete Quality Control testing results available upon request.



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