

SteriAmp® II

BIOLOGICAL INDICATOR

FOR INDUSTRIAL USE ONLY

CERTIFICATE OF ANALYSIS

SGM BIOTECH
10 Evergreen Drive
Bozeman, MT 59715
406/585-9535
www.sgmbiotech.com

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- Manufacture Date:

Expiration: 18 months from Manufacture Date

Heat Shocked Population: 10 Spores / Unit

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

Z-value: °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.