

SteriAmp® II

BIOLOGICAL INDICATOR

FOR INDUSTRIAL USE ONLY

CERTIFICATE OF ANALYSIS

SGM BIOTECH
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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- Manufacture Date:

Expiration: 15 months from Manufacture Date.

Heat Shocked Population: x 10⁶ Spores / Unit

Assayed Resistance:	D-Value ⁽²⁾	Survival	Kill	
Steam (110°C)		(3)	(3)	min
Steam (115°C)		(4)	(4)	min
Steam (121°C)		(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.

⁽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: _____