

Releasat®

BIOLOGICAL INDICATOR CULTURING SET

For Industrial Use Only

CERTIFICATE OF ANALYSIS

Reorder No: RG/100

Bacillus atrophaeus 9372⁽¹⁾

Biological Indicator for: Ethylene Oxide/Dry Heat Sterilization

Culture: 36 - 38°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

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

Releasat Gas Lot No.: RG-

Spore Strip Lot No: RGS-

Media Lot No: RM-

Manufacture Date:

Expiration Date: 12 months from Manufacture Date

Heat Shocked Population: $x 10^6$ Spores / Unit

Carrier Size: 1" x ¼" (25 mm x 6 mm)

Assayed Resistance:	D-Value ⁽²⁾	Survival	Kill	
Ethylene Oxide (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C) Oxyfume® 2000 ⁽⁵⁾		(3)	(3)	min
Dry Heat (160°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 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.

⁽⁵⁾Oxyfume 2000 is a registered trademark of Honeywell.

Certified By: _____
Quality Representative



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