LGGS, Inc.

LGGS, Inc. is an independently owned contract laboratory specializing in U.S.P. and ANSI/AAMI/ISO microbiological testing. We are dedicated to providing safe and reliable product testing. We proudly produce accurate results with the utmost efficiency for every client. Our commitment is to developing ongoing business relationships with our customers.

Ethylene Oxide Sterilization

LGGS, Inc. offers Ethylene Oxide (EO) Validation and routine testing services as outlined in ANSI/AAMI/ISO 11135-1, *Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.* The most common approach used to validate Ethylene Oxide cycles is the Overkill Method. This method is based on the inactivation of biological indicators seeded with a known concentration of *Bacillus atrophaeus* spores that have been proven more resistant than product bioburden.

Residual Testing

All EO Validations require residual testing. LGGS, Inc. tests for the presence of EO and Ethylene Chlorohydrin (ECH) residuals according to ANSI/AAMI/ISO 10993-7, *Biological evaluation medical devices – Part 7: Ethylene oxide sterilization residuals.* The table below lists allowable limits for terminally sterilized products by Ethylene Oxide

Exposure Time	Gas	Per Day	1st 24 hours	30 days	Lifetime
Limited Exposure (<24 hours)	EO ECH	4 mg 9 mg	N/A N/A	N/A N/A	N/A N/A
Prolonged Exposure (>24 hours to <30 days)	EO ECH	2 mg 2 mg	4 mg 9 mg	60 mg 60 mg	N/A N/A
Permanent Exposure (>30 days)	EO ECH	0.1 mg 0.4 mg	4 mg 9 mg	60 mg 60 mg	2.5 mg 10 mg

Validation Services

- Validation Protocol
- Population Verification
- Bioburden Method Recovery/ Validation
- Bioburden Enumeration
- Product Sterility Testing
- Sterility Validation Test (Bacteriostasis/Fungistasis)
- Biological Indicator Sterility Testing
- Residuals Testing – EO and ECH

Routine Services

- Validation Summary Report

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