Sterilisation and
Laboratory Services

Compliance
through Science

UNISURGE

Testing Capability

Working with our customers and approved suppliers, our new Technical Services Division has extensive experience in the sterilisation and scientific support industry, which means we can offer a unique insight into the services required to meet the regulatory needs of the medical device industry. The services offered include the below:

Bioburden Analysis

- Validation Protocols, execution and reports in accordance with ISO 11737.
- Product testing - Total Viable Counts via membrane filtration
- Microbial Identification

Ethylene Oxide Analysis

- Product batch release analysis for residue EtO
- Validation Protocol, execution and reports in accordance with ISO 10993-7
- Biological Indicator analysis—ISO 11135

Environmental Monitoring

- Cleanroom monitoring—Settle and contact plates
- Water TVC analysis
- Disinfection Qualification
- Working towards compliance with ISO 14644

Consultancy and Training

- Microbiological Auditing
- Bespoke customer training days.

Project Management

- Problem Solving
- Cleaning and Disinfection Studies
- Accelerated Ageing
- Endotoxin Detection via Chromogenic analysis

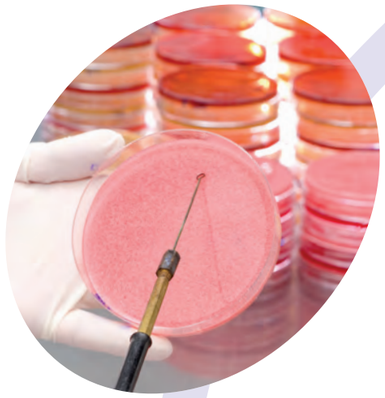
Our Technical Services team are always available to discuss your specific testing requirements.

Our Distribution Fleet

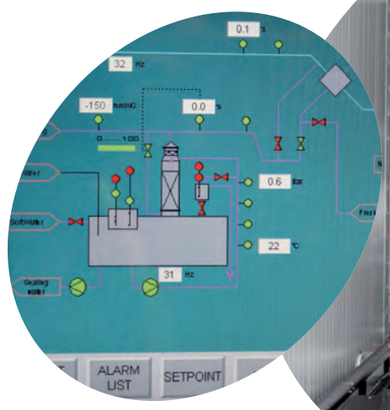
Sales and Marketing

Environmental Analysis

Biological Indicator Analysis



Bioburden Analysis



Packaging and Accelerated Ageing

Multi Site Warehousing

Cleaning and Disinfection Studies

Consultancy and Training

Endotoxin Analysis

ETO Residue Analysis

ETO Sterilisation

UNISURGE

Ethylene Oxide Sterilisation

The treatment of medical devices by ethylene oxide (EtO) has been the principle method of sterilisation and has become industry standard.

Ethylene oxide processing involves products being exposed to the gas under vacuum in a sealed chamber. This is achieved in three phases:

Phase 1 Preconditioning

Products are placed in a preconditioning cell that is designed to raise the core temperature, typically to 40-50 degree centigrade and controlled humidity. This is the first step to optimise the sterilisation process efficiency.

Phase 2 Processing

Products are moved by automatic transfer into the main chamber where the ethylene oxide gas is introduced under vacuum for a predetermined dwell time. This validated process is designed to deliver the required sterility assurance level in accordance with ISO11135.

Phase 3 Heated Aeration

In the final stage, the product is moved by automatic transfer into a preheated cell which uses circulated air to remove residual ethylene oxide within the products.

Our promise to you

As a leading provider of medical products including custom procedure packs, Unisurge International has the experience and capability of meeting your requirements for sterilisation processing.

- Validation process studies
- Technical consultancy services
- Flexible solutions
- Comprehensive laboratory services
- Pallet cycle of 1–48 dedicated or mixed cycle process capability
- Distribution and logistic network

"All at the most cost effective prices"

The Unisurge Vision

To offer each and every customer the same high standard of service whether incubating a simple environmental settle plate through to a complex Ethylene Oxide process validation.

UNISURGE

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