

## A Bespoke Ethylene Oxide Sterilisation Service



- Gentle, high-level sterilisation
- Customer-specific cycle parameters
- No minimum load size
- Separate chamber for each load
- Cycle conformity certificate
- Individually labelled items
- Sterility assured with microbiological controls
- Fast turnaround

### Features

Ethylene oxide sterilisation provides the most effective means of sterilisation without subjecting delicate items to high temperatures, pressure or humidity; thereby preserving the integrity of the product and package.

We specialise in providing customers that have **small quantities** of items to sterilise, with a **fast, efficient service**; whether they are regular or occasional users. We can adjust the sterilisation cycle to meet the **requirements of specific items**. We use chemical and biological indicators in each cycle, in conjunction with a process challenge device, designed specifically for your items. A **certificate of cycle conformity** is provided giving details of physical and microbiological parameters with **labels and lot numbers assigned to each item**. **We will never sterilise your products in the same chamber as those of another customer.**

Andersen technology enables us to achieve very short sterilisation cycle times. Consequently, your goods can be returned sterile and ready to use in as little as 4 days after you despatch them to us. We can adjust to your needs and budget: there is no specific calendar date, or minimum load requirement. We will sterilise what you need, when you need.



the future of gas sterilisation

### Full Laboratory and Validation Services

Our contract sterilisation activities are supported by laboratory testing and validation services, including contract packaging.

We are certified ISO13485:2003 / ISO9001:2008 / Annexe V Directive 93/42/EEC for validation and contract EtO sterilisation according to ISO11135:2007.

Our services include:

- Complete validation service
- Residual EtO testing
- Bioburden
- Sterility testing
- Endotoxin testing
- Shelf-life determination



## Ethylene Oxide Sterilisation

The Andersen Group have been leaders in Ethylene Oxide (EtO) sterilisation for over 50 years. We use the patented Andersen EOGas® process, utilising innovative gas diffusion technology. This enables sterilisation to occur without using a strong vacuum, or steam injection. Consequently, our **gentle cycles are suitable for very sensitive devices**. The sterilisation temperature is usually 50°C, but our **lowest temperature cycle runs at 30°C**, whilst still delivering a Sterility Assurance Level of 10<sup>-6</sup>.



EtO is released at the heart of the load within 'micro' chambers. This reduces the cycle time to between 3.5 - 16 hrs. The small amount of EtO used means that **aeration times are reduced** compared to traditional chambers. Our 'micro' chambers allow us to process **very small loads** and only charge the '**micro' chamber price**. **You only pay for what you use**.

We use the same cabinets that we offer for sale. Consequently a validation carried out for contract sterilisation is immediately transferrable to in-house sterilisation should a customer choose to purchase a cabinet at a later date. Alternatively, we can provide an additional back-up service to users of our cabinets should it be required.

## Pharmaceuticals and Medical Devices

EtO is the sterilant of choice for medical device manufactures as it offers exceptional results at low temperature combined with its ability to penetrate intricately shaped items. Our service can include manual or automatic packing in an ISO class 5 cleanroom, with the provision of rigid containers for shipping if necessary.

## Contact us to discuss your requirements or receive a quote

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## Hospitals and Laboratories

EtO can be used to sterilise most items such as fibre optics, scopes, surgical and optical instruments, plastic, rubber and electronic devices. The gentle nature of the sterilisation process can prolong the life of the most delicate instruments. We are able to cater for individual items and return them ready for use in as little as 4 days after receipt. Items for sterilisation need to be received by Andersen already cleaned and appropriately packaged.

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