STERITECH
Protecting what matters

Steritech Pty Ltd
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AGREEMENT FOR ETHYLENE OXIDE PROCESSING

This agreement and understanding is made between Steritech and the User of the ETO service. This document is a legal requirement of both parties, designating processing responsibilities as outlined in the Australian Code of Good Manufacturing Practice and international standards for ethylene oxide processing. This document and any attached additional user requirements shall form the Agreement for Ethylene Oxide Processing. ETO services will only be provided upon authorisation of this agreement by both parties.

For Completion by the User of the Ethylene Oxide Processing Service

Business (User) Name: _____

Contact Name: _____

Business Address: _____

Phone Number: _____ **Fax Number:** _____

Email Address: _____

Description of Goods: _____

Please provide a description of the product/s and the intended purpose, e.g. medical devices for sterilisation, aseptic packaging for sterilisation, imported goods for quarantine treatment, agricultural products requiring decontamination, etc.

User Responsibilities

1. Selection and specification of the EO recipe and cycle parameters required for the User's product.
2. Determining the stability, useability and efficacy of the processed product (including its packaging) for the specified EO recipe and cycle parameters, if required.
3. Qualification/validation of the selected processing cycle for the given product and re-qualification after modification or a specified period.
4. Defining the Process Specification per ISO 11135* for the products to be processed, if required.
5. If the User or User's product requires processing in compliance with ISO 11135, it is required/ mandatory the User observe items 1, 2, 3, and 4 above and the User is required to notify Steritech when products presented for EO processing are outside the current validated process specification.
6. Specification of any supplementary parameters to comply with regulatory requirements including preconditioning time, post sterilisation aeration time, biological indicator placement, loading pattern and other requirements.
7. Generation, maintenance/storage of product manufacturing records (excluding EO processing records).
8. Quality control of the User's products including taking/keeping retention samples of product, and chemical or biological testing as may be required for product sterility testing.
9. Notification of handling and storage precautions for hazardous or fragile material.
10. Delivery of product to/from Steritech and shipping specifications.
11. Responsibility for release for sale or supply to market of processed products and, if necessary, listing/ registration of therapeutic goods.
12. Notification to the other party of changes to authorised signatories to this agreement, changes to accreditation or certification status.

** ISO 11135: Sterilization of Healthcare Products - Ethylene Oxide*

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Steritech Responsibilities

1. Certified delivery of specified Ethylene Oxide recipe to User's product using the User's nominated cycle parameters. See Conditions of Supply of Ethylene Oxide Processing 5 (below) and, if attached, User's additional specific requirements.
2. Generation, maintenance, and storage (5 years) of processing records relating to the EO process, in line with ISO 13485: Medical Devices - Quality Management Systems.
3. Calibration and monitoring of the EO chambers and the EO process traceable to a national standard.
4. Quality control of the EO process and review of all agreed process parameters prior to return to the User. Maintenance of third party accreditation to an applicable standard.
5. Ensuring that EO indicator labels are placed on outside of individual cartons/pallets (as applicable).
6. Initial plant installation qualification and subsequent re-qualification and validation of the process following chamber/process modifications.
7. Investigation of complaints relating to the services provided by Steritech.
8. Notification to the other party of changes to authorised signatories to this agreement, changes to accreditation or certification status and changes to Steritech's Quality Management System or processing procedures that effect processing quality or product realisation.

Conditions of Supply of Ethylene Oxide Processing Services

1. An official order shall accompany each shipment of product and each package/pallet should be clearly marked for identification. The User shall declare to Steritech its company name and address, the nature of the product, the number of packages and the EO cycle required.
2. There are APVMA restrictions on EO processing for quarantine purposes. Steritech can provide information about this to users of this service.
3. Technical arrangements are stored in Steritech's Customer Requirements database and the User must specify any special requirements not specifically mentioned above. These arrangements should be attached as an annex to this agreement.
4. Steritech, unless otherwise directed, shall consolidate similar product, in terms of EO cycle parameters or product nature, with product from other customers for processing.
5. The Steritech certificate of processing is the User's evidence that the product has been processed as per this agreement. Steritech personnel physically verify each delivery for the identity of the client, the quantity of items to be fumigated and a client supplied reference number such as a purchase order number. Other details, such as batch code, may be transcribed from client documentation for convenience but is not verified.
6. Steritech will not be held liable for any claims made in relation to physical effects from Ethylene Oxide processing provided that Steritech is not in breach of this Agreement or acted negligently.
7. The User shall indemnify Steritech, its officers and employees against any and all actions, claims, demands, damages, reasonable costs, fines, penalties, liabilities, and obligations of whatsoever kind, resulting from or connected with the presentation of the User's product for EO processing other than contractual obligations imposed under this agreement and negligent acts or omissions of Steritech.
8. This agreement will expire three years after the latter of the dates inserted on Page 3 of this agreement and shall supersede any previous Agreement for Ethylene Oxide Processing between the User and Steritech.
9. The User understands that Ethylene Oxide is extremely flammable and requires absolute protection against energy discharges in the EO chamber. Accordingly, the customer hereby acknowledges that Ethylene Oxide processing is not intended for batteries or other stored energy devices and agrees these items will not be submitted for Ethylene Oxide processing.

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Additional User Requirements

Are the products requiring EO processing regulated by: ☐ TGA ☐ APVMA ☐ Neither

Is ISO 11135 compliance required: ☐ Yes ☐ No

Other requirements: ☐ Yes ☐ No
If 'Yes', please provide details as an attachment.

Declaration

I/we hereby accept the responsibilities and conditions stated above with respect to products presented to Steritech for Ethylene Oxide processing and the use of Steritech's Ethylene Oxide processing services.

Signature: _____

Name: _____

Position: _____

Date: _____

Any enquiries on this agreement should be addressed to Steritech's Group Quality Manager.

For Completion by Steritech

Customer Id: _____

Signature: _____

Name: _____

Position: _____

Date: _____