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AGREEMENT FOR ETHYLENE OXIDE PROCESSING

This agreement and understanding is made between **STERITECH** and the **USER** of the Ethylene oxide service (below). Such a service will be provided only upon authorisation of this agreement by both parties. This document is a regulatory requirement of both parties when processing therapeutic goods, designating processing responsibilities as outlined in the Australian Code of Good Manufacturing Practice and the current edition of ISO11135 as gazetted by the Australian government.

For Completion by User of Ethylene Oxide Service:

Company / User Name	Contact Name
Contact Number	Contact Fax
Company / User Address	Postal Address / Email

Description of Goods. (eg. Medical devices, cosmetic products, pharmaceutical raw materials, aseptic packaging, agricultural products, quarantined item...etc.)

Designation Of Responsibilities For Ethylene Oxide Processing	STERITECH	USER
1. Certified delivery of specified ethylene oxide recipe to Users merchandise using User's nominated cycle parameters. See note (g) and Customer Specific Requirements.	Yes	No
2. Qualification and validation of the processing cycle. Customers must notify Steritech when products presented for sterilisation are outside their current validation criteria.	No	Yes
3. Generation, maintenance, and storage of processing records relating to the Ethylene oxide process.	Yes	No
4. Generation, maintenance, and storage of manufacturing records for other than the Ethylene oxide process.	No	Yes
5. Calibration and monitoring of the sterilisation chamber and the delivered process traceable to a national standard.	Yes	No
6. Stability, qualification, and efficacy of merchandise (including packaging) to be processed and if required reprocessed. (Steritech can provide advice).	No	Yes
7. Specifications of supplementary parameters to comply with therapeutic regulatory requirements including preconditioning time, post sterilisation aeration time, biological indicator placement, loading pattern and any other requirements.	No	Yes
8. Quality control of Ethylene oxide process and review of all agreed process parameters prior to return to user. Maintenance of third party accreditation to current edition of ISO13485 as gazetted by the Australian government.	Yes	No
9. Quality control of users merchandise	No	Yes
10. Ensuring that Ethylene oxide indicator labels are placed on the outside wrap layer of shrink wrapped pallets or on individual cartons when supplied loose.	Yes	No
11. Placement of Ethylene oxide indicator labels on goods inside carton (if desired).	No	Yes
12. Investigation of complaints relating to the Ethylene oxide process.	Yes	No
13. Taking and keeping of retention samples of materials and products.	No	Yes
14. Chemical or biological testing (including sterility testing) of the treated merchandise.	No	Yes
15. Notification of handling, storage and transport precautions of hazardous or fragile	No	Yes

Designation Of Responsibilities For Ethylene Oxide Processing	STERITECH	USER
material and warrant of product suitability to the process.		
16. Listing, registration or inclusion of therapeutic goods including marketing authorizations.	No	Yes
17. Initial plant installation qualification and subsequent requalification. Validation of the process following chamber or process modifications.	Yes	No
18. Re-qualification of the selected cycle after modifications or a specified time.	No	Yes
19. Delivery to/from Steritech and shipment specifications.	No	Yes
20. Notification to the other party of any changes to authorised signatories to this agreement or loss of quality system accreditation or regulatory approval to supply.	Yes	Yes
21. Responsibility for release for sale or supply to market of treated materials or merchandise.	No	Yes

Conditions of supply of ethylene oxide service: (Please read carefully).

- a) An official order shall accompany each shipment of merchandise. The User shall declare to Steritech its company name and address, the nature of the merchandise, the number of packages, and the cycle required. Each package should be clearly marked for identification, for bound pallets a single identification label will suffice.
- b) Steritech, unless specifically directed, shall consolidate similar merchandise in terms of cycle parameters or product nature from other customers for processing.
- c) The User shall indemnify, defend and hold harmless Steritech, its officers and employees against any and all actions, claims, demands, damages, costs, fines, penalties, liabilities, and obligations of whatsoever kind, resulting from or connected with the presentation of the Users merchandise for treatment other than contractual obligations imposed under this agreement and negligent acts or omissions of Steritech.
- d) There are APVMA restrictions on ETO use for quarantine purposes. Steritech can provide information on this to users of our service.
- e) The Steritech certificate of processing is the User's evidence that the goods have been processed as per this agreement. Steritech personnel physically verify the identity of the client, the quantity of the goods treated 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.
- f) Technical arrangements are stored in Steritech's Customer Requirements database and the User must specify any special requirements not specifically mentioned above. These arrangements are attached as an annex to this agreement.
- g) The Steritech certificate of processing is the User's evidence that the goods have been processed as per this agreement.

Attachments: A) Customer Requirements: Yes No. **B) Other Arrangements:** Yes No

DECLARATION:

I/we hereby accept the responsibilities and conditions stated above in respect to products presented to Steritech for Ethylene oxide treatment. This agreement will expire three years after the latter date inserted below. This agreement shall supersede any previous agreements held between the User and Steritech. Any enquiries on this agreement should be addressed to the Quality Systems Manager.

Signature (Customer Management Representative)	Position	Date

Signature (Steritech Management Representative)	Position	Date

All charges relating to treatment by Steritech will be paid by:

Name: _____
Company: _____
Address: _____
Phone: _____ Fax: _____
Email: _____