QUALITY SERVICE AGREEMENT FOR ETHYLENE OXIDE TREATMENT

For Completion by the User of the Treatment Service

Company Name: _____**(User)**

Contact Full Name: _____**ABN:**_____

Business Address: _____

_____**Post Code:**_____ **State:**_____

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

Email address: _____

Service Provider: Steritech Pty Ltd

This agreement and understanding is made between Steritech Pty Ltd (ACN 007 308 027) of 160 South Gippsland Highway, Dandenong South (Steritech) and the User. This agreement is legally binding on both parties and establishes, clarifies, communicates and designates responsibilities as outlined in the applicable regulatory standards. This agreement, detailing technical and quality requirements, each Purchase Order (including related documents) issued by you and accepted by us, and any attached additional user requirements issued by you and accepted by us, shall form the Agreement for the manufacturing step of treatment and all associated services to be provided by Steritech for the User (Services) on products provided to Steritech by the User (Products). If there is any conflict between the terms of the documents listed above, the terms of the document listed first shall prevail to the extent of the inconsistency. The services will only be provided upon execution of this agreement by both parties.

The intent of the agreement is to ensure treatment activities are conducted in compliance with the latest revision of the relevant, industry specific and where applicable state, national and international legislations:

- ISO13485: Medical Devices- Quality Management Systems- Requirements for regulatory purposes
- ISO11135: Sterilization of Healthcare products- Ethylene Oxide- Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO11140-1: Sterilization of Healthcare products- Chemical Indicators- Part 1: General requirements
- PIC/S Guide to Good Manufacturing Practise (GMP) for Medicinal Products (Part I) and relevant Annexes
- PIC/S Guide to Good Manufacturing Practise (GMP) for Medicinal Products (Part II) and relevant Annexes
- Australian Code of GMP for human blood and blood components, human tissues and human cellular therapy products
- Biosecurity Act
- Approved Arrangements for 4.6- Fumigation Requirements

This agreement is valid for 36 months, effective from the date of Steritechs countersign below, and may be altered only in writing and signed by an authorised representative of each of the parties. Verbal agreements are invalid and not enforceable.

Terms of Agreement

The following symbols and terms are used within this agreement to define and identify the responsibilities held by the respective parties.

Symbol or term	Definition
✓	Responsible
×	Not Responsible

Clauses of Agreement

The sub-sections in the following table detail the technical quality agreement clauses as per the regulatory requirements pertaining to the Services, and the party(ies) responsible for each activity. Selected clauses below may not be applicable to all industries and their regulations.

Clauses	Responsibilities		
	General Access and Quality Conditions	**User**	**Steritech**
1.1	Provide reasonable access to the facility where treatment takes place.	×	✓
1.2	Provide reasonable access to all documents, procedures and records applicable to the treatment processing step and all supporting QMS processes that have been generated, implemented, completed and maintained in accordance to cGDP, all other specific industry regulations and stored for a minimum period of 5 years.	×	✓
1.3	Generation, maintenance and storage of all product manufacturing records (excluding treatment processing records) for the minimum period as defined in accordance to applicable law.	✓	×
1.4	If required under relevant regulations, maintain an appropriate Quality System so that all necessary controls and procedures are in place to ensure that the Product is treated in accordance to the required specifications.	✓	✓
1.5	Ensure Steritechs most current and valid relevant manufacturing / operating licences/ certifications are made visible to the other party.	×	✓
1.6	Immediately notify the other party, through writing, in the event any of the relevant operating licences are revoked or suspended by regulatory authorities.	×	✓
1.7	Ensure only trained and competent employees, through skills, educational background and/ or experience, execute this treatment step.	×	✓
1.8	Notify the other party, through writing, of any proposed changes to the treatment processes that may affect processing quality or product realisation. Formal acknowledgement of the communicated change should be obtained from the user prior to implementation. NOTE: no acknowledgment from the User within 30 days of notification is interpreted as implied acknowledgement and acceptance.	×	✓

1.9	Immediately notify the other party, through writing, of any changes to signatories or to any of the contact details, stated below.	✓	✓
	Supplier Management	**User**	**Steritech**
1.10	Maintain a documented procedure for the identification, approval and management of suppliers providing critical materials (e.g., EO gas, biological indicators etc) and/ or service (e.g., calibration, maintenance etc) specific to the treatment step.	×	✓
1.11	Ensure that agreements with suppliers are established, where required, to clarify and communicate responsibilities for all relevant activities, including the notification of changes.	✓	✓
1.12	Ensure that agreements with suppliers, where established, are maintained, accurate and valid for all relevant activities, including the notification of changes.	✓	✓
1.13	Conduct initial and ongoing quality evaluation assessments and approvals on suppliers of critical materials (e.g., EO gas, biological indicators etc) and critical services (e.g., calibration etc), as required. Changing the supplier of critical materials to be actioned through change control.	×	✓
1.14	Maintain a comprehensive up to date list of all suppliers deemed approved for routine use.	×	✓
1.15	Immediate notification to the other party in the event of a significant quality, safety issue or regulatory investigation relating to critical equipment or service, where product quality may be compromised.	×	✓
	Treatment	**User**	**Steritech**
1.16	Establish a unique lot numbering system for each consignment of product processed and is to appear on all traceability/ processing records for that related consignment.	×	✓
1.17	Provide an official Request Form to accompany each shipment/ consignment of product and each package/ pallet to be clearly marked for easy identification. The official Request Form must contain, at a minimum, and advise Steritech of: • customer name and address • category and name of the Product • quantity of packages/ pallets • breakdown of the batch numbers comprising said consignment • dangerous good classification in relation to the Products • storage and handling requirements in relation to the Products • EO cycle required • details of biosecurity, quarantine and relevant conditions (if applicable) An official Purchase Order may accompany each consignment solely for the purpose of invoicing. Steritech will not view a PO in place of an official Request Form.	✓	×
1.18	Selection of the EO recipe and cycle parameter specifications required for the Product intended for treatment, and if compliance to ISO11135 is required, establishment of validated process specifications.	✓	×
1.19	Determine the stability, useability and efficacy of the Product to be treated (including its packaging) for the specified EO recipe and cycle parameters.	✓	×
1.20	Define and communicate to the other party, through writing on the Request Form, all relevant process specifications as per applicable regulations for the Product received by Steritech to be treated.	✓	×

1.21	Routinely and consistently present the Product for treatment in accordance to all predetermined and/or validated specifications. It shall be noted that products that contain any liquid, viscous or other, must be completely sealed to prevent leakage. Any pallets must be tightly secured using pallet shrink wrap to reduce the risk of dislodgment, which could lead to pallet collapse.	✓	×
1.22	If the Product requires EO processing in compliance to ISO11135, adherence by the User to all clauses in this agreement under their responsibility is required, including immediately notifying Steritech, in writing, when Products are presented for treatment outside the current validated process specifications.	✓	×
1.23	Certified delivery of the EO cycle recipe to the User's Product using the User's nominated cycle parameters. See Supply Conditions below (clause 1.61)	×	✓
1.24	Labelling of Products as required by law, including placement of EO sticker labels on Products inside the cartons, if required. NOTE: Steritech does not take into consideration any markings or information on the Product or carton labels. All communication of critical product/ treatment information must be relayed to Steritech by the User on the request form only. Information communicated via any other platform will not be considered by Steritech.	✓	×
1.25	Placement of EO sticker labels on the outside of the individual cartons/ pallets, upon request by the User, if not already applied by the User.	×	✓
1.26	Specification of any supplementary parameters to comply with ISO11135 or other regulatory requirements including preconditioning time, post sterilization aeration time, biological indicator placement and any other requirements.	✓	×
1.27	Quality control of the EO process and review of all agreed / regulatory required process parameters and processing reports prior to the return of Product to the User. Maintenance of third party accreditation to applicable standards.	×	✓
1.28	Strive to ensure that the Product delivered back to the User conforms to the specified requirements including in the same visual condition in which it arrived at the Steritech facility. Any damage to the Product is investigated by Steritech and requires formal customer disposition. Ensure that any rework/ re-processing conducted under instruction by the User must meet the acceptance criteria and that all batch documentation has been reviewed. Refer to clauses 1.48 and 1.49 for further details on logistics.	×	✓
1.29	Quality control of the Product including taking and keeping retention samples of each category of Product, and chemical or biological testing as may be required for product sterility testing.	✓	×
1.30	Responsible for release for sale or supply to market of the processed Products, and if necessary, registration/ listing of the Product. Ensure that all, including but not limited to, product packaging, labelling identification, integrity and security that pertain to the relevant export/ treatment pathways are adhered to.	✓	×
	Validation and Qualifications	**User**	**Steritech**
1.31	Maintain a set of technical documentation for facilities and service equipment (including software and computer systems, if applicable), defined as critical under Steritechs Quality System, including installation and operational qualifications. Ensure that validated systems are maintained and periodically evaluated or revalidated, as required.	×	✓

1.32	Executing initial plant/ equipment installation and operational qualifications and subsequent installation and operational re-qualifications and validations following process modifications.	×	✓
1.33	Notifying the other party, in writing, prior to such equipment qualification and re-qualification events following process modifications.	×	✓
1.34	Establishing a written validation protocol for each equipment/ process qualification specifying all critical steps, acceptance criteria and reference documentation. Any variations must be documented and justified.	×	✓
1.35	Generating and filing an equipment qualification summary report by collating all related and supporting validation documents and cross referencing the corresponding protocol.	×	✓
1.36	Distribute chamber qualification reports to the User for their records, where requested.	×	✓
1.37	Initial qualification/ validation of the process or processing cycle for the given Product, and re-qualification of the process following a modification to the process specification, or routinely after a specified period, if treatment is to be in accordance to ISO11135. NOTE: this regulation require initial validation activities to be performed and as such must be crosschecked and performed prior to requesting routine treatment. Refer to clause 1.59 for further details.	✓	×
1.38	Calibration and monitoring of the EO chambers and EO process traceable to a national standard.	×	✓
1.39	Records of validation and use of critical equipment must be retained and traceable to the particular manufacturing operation stage and piece of equipment.	×	✓
1.40	Ensuring effective systems are used and documented for ensuring the premises and facility for where treatment takes place are well maintained and cleaned with records identifying cleaning status readily available.	×	✓
1.41	Ensure adequate process controls are implemented and carried out between batches of different Products to prevent cross contamination.	×	✓
1.42	Ensure effective systems are used and documented for ensuring contaminated or potentially contaminated Products are appropriately handled to mitigate cross contamination with other Products, work environment or personnel.	×	✓
	Storage and Handling- Logistics	**User**	**Steritech**
1.43	Ensure that all critical materials (e.g., EO gas, biological indicators etc) are in compliance with the specifications detailed in the associated COA/COC obtained from the approved supplier for each consignment/ delivery, and that it matches the relevant material specifications.	×	✓
1.44	Ensure that all incoming critical materials (e.g., EO gas, biological indicators etc) have been physically or administratively segregated until they have been approved and released for routine use with appropriate documentation.	×	✓
1.45	Ensure that all critical materials (e.g., EO gas, biological indicators etc) are stored, whilst onsite at Steritech, under any specialised conditions (e.g., temperature requirements) as detailed on the packaging label, incoming COA/COC or as per suppliers instruction. These conditions are required to be controlled to ensure the material quality is maintained and fit for optimum use.	×	✓

1.46	Regarding Products intended for treatment, notify Steritech, in writing, of handling and storage precautions for hazardous or fragile material. See clauses 1.17 and 1.24 for further details regarding the required communication platform.	✓	×
1.47	Regarding Products intended for treatment, notify Steritech, in writing, at least 7 days ahead of Product delivery of all specialised handling and storage requirements including temperature (i.e., chilled). These instructions must also be recorded on the approved Request form for each consignment. See clauses 1.17 and 1.24 for further details. NOTE: unless otherwise advised on the request form only, Steritech will store the Product in the open floor warehouse under uncontrolled conditions.	✓	×
1.48	Delivery to and from the Steritech facility and the defining of shipping specifications, including ensuring appropriate transportation conditions are maintained up until arrival to the Steritech facility and from the moment Product is dispatched from the same facility, and all moments thereafter. The User will be responsible for and bear the cost of this transportation. It shall be noted that goods will only be released for dispatch upon a valid lot number of invoice number presented by the driver.	✓	×
1.49	Ensure that appropriate product storage conditions are maintained from the point of arrival at the Steritech facility to the moment of Product dispatch from the same Steritech facility.	×	✓
	Inspections	**User**	**Steritech**
1.50	Conduct internal audits on the facility authorised to perform treatment to ensure these processes are appropriately implemented and effectively executed in accordance to Code to ensure that product quality is maintained.	×	✓
1.51	Conduct external/ supplier audits on the facility authorised to perform treatment to ensure these processes are appropriately implemented and effectively executed in accordance to Code to ensure that product quality is maintained, where regulation dictates.	✓	×
1.52	Immediately notify the audited party, in writing, in the event any non-conformance or deficiency identified is deemed to potentially affect the quality of the Product.	✓	✓
1.53	Distribute audit report to the audited organisation in order for the audited organisation to generate and provide formal responses (including investigational reports, root cause assessments, CAPAs and proposed target dates for rectification actions) to the identified deficiencies/ non-conformances, where regulation dictates.	✓	✓
	Deviations, Complaints and Recall	**User**	**Steritech**
1.54	Investigate, assess, record and respond to all deviations made and complaints issued from the User pertaining to the treatment service provided and/or the resulting Product.	×	✓
1.55	Investigate, assess, record and respond to all deviations made and complaints issued from the service provider pertaining to the nature of the Product, packaging and/or documentation sent for treatment.	✓	×
	Additional User Requirements and Supply Conditions		
1.56	It shall be noted that Steritech does not claim sterility of the Product. This responsibility lies with the User.		
1.57	It shall be noted that Steritech will not be held liable for any claims made in relation to physical effects from EO exposure provided that Steritech is not in breach to neither of this Agreement nor the Terms and Conditions displayed on the Steritech website at Terms and Conditions – Steritech		

1.58	It shall be noted that Steritech does not temperature map its facilities. In the event a customer nominates a specialised storage condition (i.e., chilled), Steritech will, where the service is available, store the Product in a location with the temperature set to within the Request Forms stipulated range.
1.59	It shall be noted that where treatment is requested in accordance to ISO11135, Steritech mandates the requirement for Users to initially validate their Product and process, and as such Steritech will not process a Product where no initial validation has been executed in accordance to that regulations requirements. Re-validation activities, unless a requirement under the stated regulation, will not be mandated by Steritech. This decision lies with the User. Should no re-validation be requested by the User, Steritech cannot provide confirmation that the entire product load has received a distribution of gas exposure within the treatment specification limits.
1.60	It shall be noted that where regulation allows, Steritech may consolidate the Product with similar products (from other customers) in terms of exposure requirements, EO cycle parameters or product nature, unless otherwise directed in writing on the Request Form.
1.61	It shall be noted that Steritech's 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 treated and a client supplied reference number such as a purchase order number. Other details, such as batch code, may be transcribed from the client documentation for convenience but is not verified by Steritech.
1.62	It shall be noted that there are APVMA restrictions on EO processing for quarantine purposes. Steritech can provide information about this to the User.
1.63	It shall be noted that Technical Arrangements are stored in Steritech's Customer Requirements database and the User must specify in this agreement (see below for designated field) any special requirements relating to the Services and/or Products that are not specifically mentioned above. Steritech reserves the right to accept or reject the requested additional technical arrangements at its discretion.
1.64	The User acknowledges and agrees that: A. Ethylene Oxide (EO) gas is extremely flammable and requires absolute protection against energy discharges in the EO chamber; B. EO processing is not intended for batteries or other stored energy devices.
1.65	It shall be noted that Steritech reserves the right to examine the contents of any Product(s) in the event such Product has resided on hold at any Steritech facility for a time period exceeding six months. Steritech will then coordinate with an authorised and licenced third party to undertake appropriate disposal of said Product.
1.66	It shall be noted that each Steritech site carries sizing and weight limitations for their chambers and conveyer systems (Steritech site can provide these limitations upon enquiry from the customer), for which the customer must adhere to when preparing their consignments for delivery to Steritech. Consignments that exceed these limitations may require manual intervention in which case may incur additional costs, or could be rejected at receipt and returned to the customer for re-work. It shall also be noted that for Occupational Health and Safety purposes, an individual carton must not exceed 25kg in weight, and where possible be marked as heavy.
1.67	It shall be noted that should the User wish to propose any addendums to this agreement or to the detail in any clauses above, these must be communicated to Steritech (see below for designated field) and will be assessed for suitability prior to countersigning this agreement. Steritech reserves the right to accept or reject the requested addendums at its discretion.

Are any additional Technical Arrangements required as per clause 1.63 (tick one)? ☐ Yes ☐ No

If Yes, specify details below.

Are any addendums required to this agreement as per clause 1.67 (tick one)? ☐ Yes ☐ No

If Yes, reference relevant clause and specify addendum details below.

For Completion by the User-

Best contacts at the User company

Accounts Dep. Representative full name:_____

Email:_____Phone:_____

Operations Dep. Representative full name:_____

Email:_____Phone:_____

Quality Dep. Representative full name:_____

Email:_____Phone:_____

Treatment certificates to be sent to:

If not specified below, treatment certificates will be sent to the Quality Dep. contact stated above

Representative full name:_____

Email:_____Phone:_____

I am authorised to sign this agreement on behalf of the User Company and hereby acknowledge and accept the details stated throughout this Service Agreement as the Terms and Conditions displayed on the Steritech website at Terms and Conditions – Steritech. We, as the User further commit to upholding those clauses where responsibility is assigned to the User.

_____	_____
Name of Authorised representative	Title of Authorised representative
_____	_____
Signature of Authorised representative	Date of execution (dd/mm/yyyy)

For Completion by Steritech-

Best contacts at Steritech

Accounts Dep. Representative full name:_____

Email:_____Phone:_____

Operations Dep. Representative full name:_____

Email:_____Phone:_____

Quality Dep. Representative full name:_____

Email:_____Phone:_____

I am authorised to sign this agreement on behalf of Steritech and hereby acknowledge and accept the details stated throughout this Service Agreement. We, as Steritech further commit to upholding those clauses where responsibility is assigned to Steritech. I have verified that the User has signed this Service Agreement.

_____	_____
Name of Authorised representative	Title of Authorised representative
_____	_____
Signature of Authorised representative	Date of execution (dd/mm/yyyy)

•••• *upon completion of acknowledgment, this signed agreement is to be filed with both parties* •••••