STERITECH
Protecting what matters

Steritech Pty Ltd
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www.steritech.com.au

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AGREEMENT FOR IRRADIATION PROCESSING

This agreement and understanding is made between Steritech and the User of the irradiation 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 irradiation processing. This document and any attached additional user requirements shall form the Agreement for Irradiation Processing. Irradiation services will only be provided upon authorisation of this agreement by both parties.

For Completion by the User of the Irradiation 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 of the irradiation, e.g. medical devices for sterilisation, pharmaceutical raw materials for microbial reduction, aseptic packaging for sterilisation, imported goods for quarantine treatment, polymers for cross-linking, etc.

User Responsibilities

1. Selection of the minimum required dose and, if necessary, establishment of maximum allowable accumulated dose and routine dosimetry dose limits.
2. Determining the stability, useability and efficacy of the irradiated product (including its packaging) for the required total accumulated dose to be delivered to the product, if required.
3. Qualification/validation of the process for the given product, and requalification of the process following a modification of the process specification or a Cobalt-60 source replenishment, if required.
4. Defining the Process Specification per ISO 11137* for the products to be irradiated, if required.
5. If the User or User's product requires irradiation processing in compliance with ISO 11137, it is required/mandatory the User observe items 1, 2, 3, and 4 above and the User must to notify Steritech when products presented for irradiation are outside the current validated process specification.
6. Generation, maintenance/storage of product manufacturing records (excluding irradiation processing records).
7. 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.
8. Placement of irradiation indicator labels on product inside cartons, if required.
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 irradiated 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 11137: Sterilization of Healthcare Products - Radiation*

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Steritech Responsibilities

1. Certified delivery of radiation dose to User's product to a specified level in compliance with User and regulatory requirements (ISO 11137), if indicated as required as an additional requirement below. See Conditions of Supply of Irradiation Processing items 4 and 5 (below).
2. Generation, maintenance, and storage (5 years) of processing records relating to the irradiation process, in line with ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.
3. Calibration and monitoring of the dosimetry system traceable to a national standard.
4. Quality control of the irradiation 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 irradiation 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 including source replenishment.
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 Irradiation Processing Services

1. An official order shall accompany each shipment of product and each package/pallet should be clearly marked for identification and the User shall advise Steritech its company name and address, the nature of the product, the number of packages, the minimum dose required and, if required by regulation, the products maximum acceptable dose and routine dosimetry dose limits.
2. Foods for human consumption are accepted for irradiation on the condition that the signatory below certifies that they comply with the restrictions of the Food Standards Code. The User must declare any foods to Steritech prior to processing.
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 density or exposure requirements 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 irradiated, the density of each new item 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 ionising radiation 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 irradiation 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 Irradiation Processing between the User and Steritech.

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Additional User Requirements

Are the products requiring irradiation regulated by: ☐ TGA ☐ APVMA ☐ Neither

Is ISO 11137 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 irradiation processing and the use of Steritech's irradiation 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: _____