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AGREEMENT FOR IRRADIATION PROCESSING

This agreement and understanding is made between **STERITECH** and the **USER** of the irradiation service (below). Such a service will be provided only upon authorisation of this agreement by both parties. 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.

For Completion by User of Irradiation Service:

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

Description of Goods and their intended purpose. (eg. Medical devices, cosmetic products, pharmaceutical raw materials, aseptic packaging, agricultural products, quarantined item, food...etc.) NB: If food please state purpose for irradiation (eg decontamination, disinfestation).

Designation Of Responsibilities For Irradiation Processing	Steritech	User
1. Certified delivery of radiation dose to Users merchandise to a specified level in compliance with User and regulatory requirements in line with ISO11137. See note (g).	Yes	No
2. Selection of the minimum required dose and, if necessary, establishment of maximum allowable accumulated dose. (Steritech can provide advice if required). (This is a mandatory requirement for therapeutic goods).	No	Yes
3. Qualification and validation of the products, selected dose and/or dose range. Therapeutic customers are required to notify Steritech when products presented for sterilisation are outside their current validation criteria.	No	Yes
4. Generation, maintenance, and storage (5 years) of processing records relating to the Irradiation process, in line with ISO13485.	Yes	No
5. Generation, maintenance, and storage of manufacturing records for other than the Irradiation process.	No	Yes
6. Calibration and monitoring of sterilisation dosimetry traceable to a national standard.	Yes	No
7. Stability, qualification, and efficacy of merchandise (including packaging) to be processed, and if necessary reprocessed. (Steritech can provide advice)	No	Yes
8. Specified requirements including routine dosimetry limits, dose rate, time of exposure, number of exposures and other parameters for therapeutic goods.	No	Yes
9. Quality control of Irradiation process and review of all agreed process parameters prior to return to user. Maintenance of third party accreditation to an applicable standard.	Yes	No
10. Quality control of users merchandise.	No	Yes
11. Ensuring that Irradiation indicator labels are placed on outside of individual cartons/pallets (as applicable).	Yes	No
12. Placement of Irradiation indicator labels on goods inside carton (if desired).	No	Yes
13. Investigation of complaints relating to the Irradiation process.	Yes	No
14. Taking and keeping of retention samples of materials and products.	No	Yes
15. Chemical or biological testing (including sterility testing)	No	Yes

Designation Of Responsibilities For Irradiation Processing	Steritech	User
16. Notification of handling, storage and transport precautions of hazardous or fragile material.	No	Yes
17. Inclusion, listing and/or registration of therapeutic goods, evaluation of Steritech's suitability as a contractor.	No	Yes
18. Initial plant installation qualification and subsequent re-qualification and validation of the process following chamber/process modifications including source replenishment.	Yes	No
19. Re-qualification of the process after modifications. For therapeutic goods this includes loading patterns, dose mapping and verification dose audits.	No	Yes
20. Delivery to/from Steritech and shipment specifications.	No	Yes
21. Notification to the other party of changes to authorized signatories to this agreement or loss of third party accreditation or certification status changes or is revoked.	Yes	Yes
22. Responsibility for release for sale or supply to market of treated materials or merchandise.	No	Yes

Conditions of supply of irradiation service: (Please read carefully).

- (a) An official order shall accompany each shipment of merchandise (each package should be clearly marked for identification). The User shall declare to Steritech its company name and address, the nature of the merchandise, the number of packages, the minimum dose required and, if required by Regulation, the maximum dose to which the merchandise can be exposed.
- (b) Steritech will not be held liable for any claims made in relation to physical effects from ionising radiation.
- (c) Steritech, unless otherwise directed, shall consolidate similar merchandise in terms of density or exposure from other customers for processing.
- (d) 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.
- (e) 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. Currently treatment is limited to herbs, spices, herbal teas and some tropical fruits. These goods require labelling after treatment indicating they have been treated with ionising electrons. The User must declare any foods to Steritech prior to processing.
- (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 should be 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. Steritech personnel physically verify each delivery for the identity of the client, the quantity of the goods treated, 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.

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 Irradiation 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.

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Signature (Customer representative)

Position

Date

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Signature (Steritech Representative)

Position

Date

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

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