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AGREEMENT FOR HEAT PROCESSING

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

For Completion by User of Heat 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 Heat Processing	STERITECH	USER
1. Certified delivery of specified heat parameters to Users merchandise using User's nominated time-temperature parameters. See note (g) and Customer Specific Requirements.	Yes	No
2. Qualification and/or validation of the processing time-temperature conditions. Customers must notify Steritech when products presented for processing are significantly different to product previously processed.	No	Yes
3. Generation, maintenance, and storage of processing records relating to the Heat process.	Yes	No
4. Generation, maintenance, and storage of manufacturing records for other than the Heat process.	No	Yes
5. Calibration and monitoring of the processing 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 maximum treatment time, post processing cooling time, test pack placement, loading patterns and any other requirements.	No	Yes
8. Quality control of Heat process and review of all agreed process parameters prior to return to user. Maintenance of third party accreditation to the current edition of ISO9001 as gazetted by the Australian government.	Yes	No
9. Quality control of users merchandise	No	Yes
10. Ensuring that identification labels are placed on the outside wrap layer of shrink wrapped pallets or on individual cartons when supplied loose.	Yes	No
11. Placement of process indicator labels on goods.	No	Yes
12. Investigation of complaints relating to the Heat process.	Yes	No
13. Taking and keeping of retention samples of materials and products.	No	Yes
14. Chemical or biological testing of the treated merchandise.	No	Yes

Designation Of Responsibilities For Heat Processing	STERITECH	USER
15. Notification of handling, storage and transport precautions of hazardous or fragile material and warrant of product suitability to the process.	No	Yes
16. Compliance with AQIS QAP requirements for transport to and from Steritech of goods under AQIS direction.	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 time-temperature conditions 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 heat 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 time-temperature conditions 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 time-temperature conditions or product nature from other customers for processing.
- c) Steritech will not be held liable for any claims made in relation to physical effects from heat treatment
- 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) 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 an AQIS direction number, 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 Heat 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: _____