

EXCLUSIVE PROCESSING, LAB AND CONSULTING AGREEMENT

THIS AGREEMENT (the “*Agreement*”) is entered into on the Effective Date (as defined below) between _____, maintaining an address at _____ (the “*Customer*”), and the International Sterilization Laboratories, LLC, a Florida Limited Liability Company maintaining an address at 217 Sampey Road, Groveland, FL 34736 (“*ISL*”), (collectively Customer and ISL are referred to as the “*Parties*”).

1.0 Terms of Agreement.

This Agreement will commence on the date that the applicable Schedule is signed by Customer and ISL (the “*Effective Date*”) and will continue for a period of _____ years unless provided otherwise in the applicable Schedule. After the initial term, this Agreement shall automatically renew for successive one year periods, unless Customer or ISL provides written notice to the other party, at least ninety (90) days prior to the end of the initial or any renewal term that the Agreement shall not be renewed. Notwithstanding anything herein to the contrary, in the event that Customer fails to process under this Agreement with ISL for twelve (12) continuous months, this Agreement will automatically terminate at the end of the then existing term.

2.0 Purchase And Sale Of Work

- 2.1 *Purchase and Sale of Work.* During the term of this Agreement, including any extensions thereof and subject to the terms and conditions set forth herein and in each of the applicable Schedules, Customer agrees to purchase from ISL and ISL agrees to perform for Customer all of Customer’s requirements for which Customer has submitted to ISL a forecast of processing work (the “*Work*”) as identified in Schedules A, attached hereto, for the products (the “*Products*”), manufactured, assembled, distributed or otherwise produced at Customer’s _____ facility and identified in Schedule A, as such Schedule is amended in writing from time to time by the Parties.. In the event that Customer acquires or develops new products which require the Work, Customer agrees to inform ISL of such requirements and afford ISL the opportunity to submit a proposal to perform the Work for such products.
- 2.2 *Annual and Monthly Forecasts.* Customer shall provide ISL with a monthly forecast of its requirements for the Work for ISL at its Groveland, Florida facility for each calendar year covered by this Agreement no later than August 1 of the preceding year. Within thirty (30) days after receipt of Customer’s forecast, ISL will notify Customer as to whether and to what extent it will be able to provide the Work for Customer’s forecasted needs pursuant to the Service level requirements set forth in Section 2.3 of this Agreement. If ISL does not notify Customer, ISL shall be deemed to have agreed to provide the Work for Customer’s forecasted needs pursuant to the Work level requirements set forth in Section 2.3 of this Agreement.
- 2.3 *Work Level Requirement.* With respect to Work requested pursuant to Section 2.2 above, and provided that Customer has honored all obligations in this Agreement, ISL shall complete the Work within the time frame set forth in the applicable Schedules for Products delivered by Customer not in excess of the agreed upon product delivery forecast for the month pursuant to Section 2.2 of this Agreement. In the event Customer delivers to ISL, during a week, Product in excess of the prorated volume (based on that month’s forecast divided by the number of working days in such month) set forth in the agreed upon forecast provided pursuant to Section 2.2 of this Agreement, ISL agrees to use commercially reasonable efforts to complete the Work for such excess within the time frames set forth in Schedule A. For purposes of this Agreement and unless agreed upon otherwise, a working day is any day, excluding Saturday and Sunday, during which ISL’s facility to which the Product is shipped by Customer provides the Work. The “turn around period” shall commence on the working day and at the time Product is received at ISL’s facility and shall end on the working day and at the time the Product is removed from ISL’s EO chamber.

3.0 Prices for Work; Payment Terms

3.1 Prices, Payment Terms.

- (a) During the first twelve (12) months after the Effective Date, ISL shall provide the Work to Customer at the prices set forth in Schedule A. Prices do not include taxes or the costs of shipping Products to and from ISL's facility. All taxes and costs related to shipping shall be the exclusive responsibility of Customer. Title to and risk of loss of the Products shall remain with the Customer at all times.
- (b) ISL will invoice the Customer for the Work on a regular basis. The Customer shall pay each invoice thirty (30) days from the date of the invoice. Any amount not so paid shall accrue compound interest at a rate of 1½% per month from the date the invoice is past due. In the event Customer fails to timely pay any invoice, ISL reserves the right, at its option with or without notification to the Customer, to: (i) refuse to perform further Work for the Customer, (ii) perform further Work for the Customer on a cash in advance or cash on delivery basis, (iii) withhold the shipment of Product in ISL's possession until all past due invoices are paid, and (iv) make use of any other remedies legally available to it. In addition to any amounts owed for the Work, Customer shall also reimburse ISL for any and all costs that arise out of or in connection with ISL's successful assertion of its rights hereunder, including reasonable attorneys' fees and court costs.

4.0 Performance of Work

- 4.1 *Work Requirements.* ISL shall perform the Work with respect to such Products as set forth in Schedule A. The Parties may agree to modify the Work requirements for any Product at any time and they may agree upon additional Work requirements for new Products. No Work requirements, modifications or additions shall become effective and binding upon the Parties until they have been mutually agreed upon in writing in new or amended Schedule A. Customer shall notify ISL of any and all changes in the composition of or materials in the Products or their packaging prior to shipping any such Products to ISL. Any and all increase costs arising out of any Customer changes shall be the Customer's sole responsibility.
- 4.2 *Validation of Work Requirements.* With respect to the Work provided pursuant to Schedule A. Customer acknowledges that the U.S. Food and Drug Administration requires, and Customer agrees, that Customer shall have exclusive responsibility for the validation of such Work requirements for Products prior to the commencement of processing at ISL and commercial distribution of such Products. With respect to the Work provided pursuant to Schedule A, the Customer acknowledges and agrees that it is solely and exclusively responsible for the validation of Work, product sterility and the integrity and adequacy of the Product and its packaging and labeling.
- 4.3 *Shipment of the Products by ISL.* ISL shall cause the Products to be shipped in accordance with Customer's written instructions. When shipping the Products, ISL shall include documents specifying the name of the Products, the number of units of the Products, and the lot number. Unless agreed upon in writing, ISL shall not be required to break up multiple-pallet loads or individual pallets prior to shipment.
- 4.4 *Storage of the Products by ISL.* ISL will store the Products on its premises for a period of up to five (5) business days beyond the business day when the Work is completed for ISL's customary storage fee. Unless otherwise specified in the applicable Schedules, the Customer agrees that pallets stored by ISL may be doubled-stacked. If ISL has not received written instruction regarding the shipment of the Products by the expiration of the five (5) business day period after the completion of the Work, ISL shall be free, at ISL's option, to (i) continue to store the Products on its premises at ISL's customary storage price, (ii) cause the Products to be stored at an outside warehouse selected by ISL, with all shipping and storage costs to be borne by the Customer, or (iii) ship the Products to the Customer at the Customer's expense.
- 4.5 *Non-Sterile Markings.* For Work performed pursuant to Schedule A, Customer shall cause all Products to be shipped and marked in compliance with all regulatory requirements with respect to the transportation of non sterile products. After the completion of the Work performed pursuant to Schedule A, ISL will conspicuously mark each pallet, carton or other designated unit to indicate the articles have been treated and that they have not been released from quarantine. Customer agrees that it will leave the ISL's attached label affixed to each pallet, carton or other container in quarantine until it has received a certificate of specification compliance from its testing laboratory.

4.6 *Compliance with Laws.* Each of the Parties agrees at all times to conduct its operations in compliance with the applicable requirements of 21 CFR Part 801.150 (Medical Devices: Processing, Labeling or Repacking), 21 CFR Part 820 (Quality System Regulation: General), or any successor regulations as well as any other applicable laws and regulations.

4.7 *Emergency Contacts.* In the event there is a deviation in a processing cycle it will be necessary to contact Customer during business and non-business hours to determine whether Customer desires to complete processing or terminate the processing cycle. Set out below are the names, titles and emergency contact telephone numbers of Customer's employees who may authorize the termination or continuation of the processing cycle:

Name: _____

Name: _____

Title: _____

Title: _____

Phone Number: () _____

Phone Number: () _____

5.0 Regulatory and Compliance Matters

5.1 *Regulatory Compliance.* During the provision of services hereunder, Customer will do the following:

- (a) comply with all applicable laws, regulations and orders, including but not limited to all Federal, state statutes and regulations, rulings and executive or administrative orders, paying particular attention to the Federal Food, Drug and Cosmetic Act and all regulations issued pursuant there to and administered by the Food and Drug Administration ("FDA");
- (b) inform the FDA or any other inquiring regulatory agency that ISL acts as an independent contractor for Customer;
- (c) inform the FDA or any other inquiring regulatory agency that ISL processes Customer's product in accordance with the treatment specifications developed, validated and provided by Customer;
- (d) inform the FDA (and such other agencies as may be appropriate) as required by 21 CFR Subpart E § 801.150, that a written agreement has been entered into between Customer and ISL containing the elements required therein, including those pertaining to recordkeeping (collectively "Regulatory Notification").

5.2 *Agency Notifications.* Should ISL determine that Customer failed to provide Regulatory Notification as required above, then ISL may, at its election, but without any obligation to do so, provide Regulatory Notification to any and all governmental agencies that ISL deems appropriate under the circumstances. Provider shall have no liability to Customer for providing such notifications.

5.3 *Customer Maintenance of Proper Registration, Permits and Licenses.* Customer represents and warrants to ISL that it possesses all required registrations, permits licenses and approvals from all federal, state, and local agencies for Customer to operate and legally conduct business with ISL. Customer shall indemnify, protect, defend and hold harmless ISL from any failure whatsoever by Customer to obtain such registrations, permits, licenses and approvals, including, but not limited to, those registrations, licenses, permits and approvals necessary for ISL to provide the services for Customer contemplated by this Agreement ("Customer's Required Licenses").

5.4 *Reimbursement for Customer's Failure to have Required Registrations, Permits and Licenses.* In the event that ISL is charged or fined by any governmental authority in whole or in part as a consequence of the failure of Customer to have the appropriate Customer Required License, Customer shall immediately upon demand reimburse ISL for all legal cost associated with defending itself against such charge and with respect to the imposition of any resulting fine. Further, in the event that ISL is required to pay any fee or fine in as a consequence in whole, or in part, of Customer not having the appropriate Customer Required License, Customer will reimburse ISL for the full amount of any such fees or fines paid by ISL.

5.5 *ISL Maintenance of Proper Registration, Permits and Licenses.* ISL represents and warrants to Customer that ISL possesses all of the registrations, permits and licenses required to provide the services for Customer ("ISL Required Licenses") and will maintain the ISL Required Licenses in effect and in good standing throughout the term of this Agreement. Customer hereby acknowledges that ISL has informed Customer that ISL is not legally authorized to provide processing services for food, cosmetics or drug (prescription or over the counter) products and customer will not tender such products to ISL for processing.

5.6 *Customer Representation and Warranty of Compliance.* The parties acknowledge that any device shipped to ISL and transported in interstate commerce, pursuant to this Agreement, is non-sterile and is being shipped to ISL for further processing. Customer further represents and warrants that all products delivered to ISL by Customer can be processed in accordance with the terms of this Agreement without violation of any applicable laws or regulations.

6.0 Confidential Information.

The Parties each acknowledge that in the course of performing under and pursuant to this Agreement, it may obtain certain confidential and/or proprietary information belonging to the other party, its affiliates or customers. Subject to the exceptions set forth hereinafter, each party agrees that all information communicated to it by the other party shall be received in strict confidence, shall be used only for the purposes of this Agreement and shall not be disclosed by it, its agents or employees during the term of this Agreement and for three (3) years after the expiration or termination of this Agreement without the prior written consent of the disclosing party, except as may be necessary by reason of legal or regulatory requirements beyond the respective parties' reasonable control. The foregoing obligations of confidentiality shall not apply to information which: (a) is or becomes available to the public through no act or omission by the receiving party; (b) was already known by the receiving party at the time of the disclosure by the disclosing party, as evidenced by the receiving party's written records existing prior to the date of disclosure by the disclosing party; (c) is lawfully obtained from a person or entity not a party to this Agreement who is lawfully entitled to disclose the information; (d) is approved for release by written authorization of the disclosing party, but only to the extent of such authorization; (e) is required by law or regulation to be disclosed to any person; (f) is disclosed in response to a valid order of a court or other governmental body or any political subdivisions thereof; (g) is developed independently by the receiving party or its affiliates by personnel not having access to the disclosing party's confidential information; or (h) is disclosed in connection with the merger, combination or sale of a party or of all or substantially all of a party's assets; provided that in the case of (h): (i) the party to whom such information is provided first enters into a confidentiality agreement that has terms and conditions that are the same or more restrictive than those in this Section 5 and (ii) the party to whom such information is provided is not a direct competitor of the other party to this Agreement.

6.0 Limited Warranty; Liability for Product Damage; Warranty Disclaimer; Limitation of Liability

6.1 Limited Warranty.

- (a) With respect to the Work performed pursuant to Schedule A, ISL warrants to the Customer that it and its controllable process parameters will process the Products in accordance with the processing specifications referred to in Schedule A.
 - (b) With respect to Schedule A, the Customer acknowledges that the foregoing limited warranty in this Section 6.1 is personal to the Customer and that such limited warranty may be enforced against ISL only by the Customer, and not by any third party (including, without limitation, Product resellers and end-users).
 - (c) If ISL becomes aware of any non-conformity with the limited warranty set forth in Section 6.1(a) within ninety (90) days of shipment from ISL of the Product subject to the warranty claim, then Customer's sole and exclusive remedy, and ISL's sole liability to the Customer, shall be limited to (i) re-performing the Work with respect to such Product at ISL's expense, if the Product is capable of having the Work re-performed or (ii) if the Product is not capable of having the Work re-performed, subject to an overall aggregate limit as provided in Section 6.4(a), crediting the Customer for its direct manufacturing cost of the Product which is damaged by the Work nonconformance and which need to be replaced, up to a maximum credit equal to **five (5)** times the Work charge for such Product, as stated in Schedule A. ISL will re-perform the Work with respect to such Product only after receiving the Customer's written authorization to do so.
- 6.2 With respect to Schedule A, if Product is damaged by ISL as a result of physical mishandling by ISL, then Customer's sole and exclusive remedy, and ISL's sole liability to the Customer, shall be limited to the amount set forth in Section 6.1(c)(ii). Customer shall use best efforts to keep all such costs to a minimum by refurbishing and/or repackaging wherever feasible. Customer must present a written request with sufficient information as to the damage claim to ISL for reimbursement for damages under this Section 6.2 within ninety (90) days of the damage occurrence or lose its indemnification rights with respect to the damaged Product. ISL

will provide compensation to Customer within thirty (30) days of ISL' receipt of satisfactory written notification and supporting documentation provided the damages are not in dispute.

6.3 *Warranty Disclaimer.* ISL MAKES NO REPRESENTATION, GUARANTEE OR WARRANTY, EXPRESS OR IMPLIED, OTHER THAN THE LIMITED WARRANTY CONTAINED IN SECTION 6.1. IN PARTICULAR, ISL MAKES NO REPRESENTATION, GUARANTEE OR WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO OR CONCERNING THE STERILITY OF THE PRODUCTS OR DEGREE OF STERILIZATION, THE ADEQUACY OF THE SAMPLES TENDERED FOR TESTING FOR ANY SPECIFIC USE OR APPLICATION, THAT DETERMINATION BEING THE SOLE RESPONSIBILITY OF THE CUSTOMER, NOR AS TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF PRODUCTS AFTER PROCESSING BY ISL. THE CUSTOMER ACKNOWLEDGES AND AGREES THAT ANY OPINIONS EXPRESSED BY ISL ARE RECOMMENDATIONS ONLY AND FINAL APPROVAL OF SUCH RECOMMENDATIONS ARE THE SOLE AND EXCLUSIVE RESPONSIBILITY OF CUSTOMER. THE CUSTOMER ALSO ACKNOWLEDGES AND AGREES THAT THE CUSTOMER IS SOLELY AND EXCLUSIVELY RESPONSIBLE FOR PRODUCT STERILITY ASSURANCE, THE INTEGRITY AND ADEQUACY OF PRODUCT AND ITS PACKAGING AND THE VALIDATION OF WORK, LABELING AND THE INTEGRITY AND ADEQUACY OF THE SAMPLES SUBMITTED FOR TESTING FOR ANY SPECIFIC USE OR APPLICATION.

6.4 *Limitation of Liability.*

- (a) WITH RESPECT TO THE WORK PERFORMED PURSUANT TO SCHEDULE A, IN NO EVENT SHALL ISL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR OTHER SIMILAR DAMAGES, INCLUDING BUT NOT LIMITED TO DAMAGES ARISING FROM DEATH, BODILY INJURY, PROPERTY DAMAGE (OTHER THAN DAMAGE TO THE PRODUCT AS PROVIDED IN SECTION 6.1(c)), LOSS OF PROFITS OR REVENUE OR LOSS OF USE OF THE PRODUCT. WITH RESPECT TO THE WORK PERFORMED PURSUANT TO SCHEDULE A, SUBJECT TO THE REQUIREMENTS OF SECTION 6.1(c), ISL' S AGGREGATE LIABILITY UNDER OR AS A RESULT OF THIS AGREEMENT SHALL NOT EXCEED THE GROSS PROCEEDS RECEIVED FROM THE CUSTOMER DURING THE TWELVE MONTH PERIOD WHEN THE INCIDENT GIVING RISE TO ISL' S LIABILITY OCCURS.
- (b) WITH RESPECT TO THE WORK PERFORMED PURSUANT TO SCHEDULE A, IN NO EVENT SHALL ISL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR OTHER SIMILAR DAMAGES, INCLUDING BUT NOT LIMITED TO DAMAGES ARISING FROM DEATH, BODILY INJURY, PROPERTY DAMAGE (OTHER THAN DAMAGE TO THE PRODUCT AS PROVIDED IN SECTION 6.1(e)(ii)), LOSS OF PROFITS OR REVENUE OR LOSS OF USE OF THE PRODUCT. WITH RESPECT TO THE WORK PERFORMED PURSUANT TO SCHEDULES A-L SUBJECT TO THE REQUIREMENTS OF SECTION 6.1(e)(ii), ISL' AGGREGATE LIABILITY UNDER OR AS A RESULT OF THIS AGREEMENT SHALL NOT EXCEED THOSE AMOUNTS SET FORTH IN SECTION 6.1(c)(ii) ABOVE.

7.0 Termination

- 7.1 *Termination for Material Breach.* If either party is in material breach of any of its obligations under this Agreement, the other party may give written notice that the Agreement will be terminated if the breach is not cured within thirty (30) days. If such notice is given and the breach is not cured within the above periods, then the party not in breach shall have the right to immediately terminate this Agreement. Additionally, ISL may terminate this Agreement in the event that Customer is in breach of any other agreement with ISL and such breach is not cured within thirty (30) days of written notice by ISL to Customer of such breach.
- 7.2 *Termination for Failure to Satisfy Minimum Volumes.* If the Parties have agreed to minimum annual Product volumes in the Schedule A and Customer fails to meet the committed volumes, Customer shall be deemed to be in material breach of this Agreement. In such case, ISL shall have the right to terminate this Agreement upon thirty (30) days notice.
- 7.3 *Termination upon Insolvency.* This Agreement shall be terminated effective immediately upon delivery of written notice by a party of such termination if any of the following occurs: (i) the institution by or against the other party of insolvency, receivership or bankruptcy proceedings, (ii) such other party's making an assignment

for the benefit of creditors, or (iii) the dissolution of such other party. There shall be no opportunity to “cure” or any requirement for advance notice of termination under this Section 7.3.

7.4 *No Waiver of Termination Rights.* Any delay by either party in sending any of the notices specified in Sections 7.1, 7.2 or 7.3 shall not constitute any waiver of the sending party’s right to terminate this Agreement.

7.5 *Termination Not Unfair or Abusive.* The Parties agree that any termination hereof according to the formalities specified herein, and based on the conditions required by the provision under which such termination is effected, shall not constitute an unfair or abusive termination or create any liability not set forth in this Agreement of the terminating party to the other party.

7.6 *Survival of Certain Rights and Obligations.* Neither the expiration nor any termination of this Agreement for whatever cause shall affect any rights or obligations of either party which have accrued as of the Effective Date of such expiration or termination, nor shall it affect any rights or obligations of either party which are intended by the parties to survive such expiration or termination, including without limitation the rights and obligations of the parties under Sections 5, 6 and 8.3 hereof.

8.0 General Provisions

8.1 *Notices.* Any notice, request, information or other document to be given hereunder to any of the parties by any other party shall be in writing and delivered personally or sent by registered or certified mail, postage prepaid, as follows:

If to Customer, addressed as follows:

[Customer’s Name]

Street Address

Office Number

City, State, Zip

Attention:

Contact Individual(s)

If to ISL, addressed as follows:

International Sterilization Laboratory, LLC
217 Sampey Road
Groveland, FL 34736

With a copy to:

ISL c/o Aso, LLC
300 Sarasota Center Boulevard
Sarasota, FL 34240
Attention: General Counsel

Any party may change the address to which notices hereunder are to be sent by giving written notice of such change of address in the manner herein provided for giving notice. Any notice delivered personally shall be deemed to have been given on the date it is so delivered, and any notice delivered by registered or certified mail shall be deemed to have been given on the date it is received.

- 8.2 *Governing Law.* This Agreement is governed by the laws of the State of Florida without giving effect to any conflicts of law rules or principles. Where there exist any claim or dispute which the Parties cannot themselves amicably resolve, each party irrevocably submits itself to the jurisdiction of the state courts of the State of Florida located in or having jurisdiction over Sarasota County or to the federal courts sitting in the Federal District of Florida in which Sarasota County is located and irrevocably agrees that all claims or disputes arising hereunder shall be heard and determined only in and by said courts. Each party irrevocably waives and agrees not to assert by way of motion, as a defense or otherwise in any such action or proceeding, and claim that such party is not personally subject to jurisdiction of said courts, that such action or proceeding is brought in an inconvenient forum, that the venue of such action or proceeding is improper or that this Agreement may not be enforced in or by such courts.
- 8.3 *Indemnification* The Customer agrees to indemnify, defend and hold ISL, its parent, subsidiary and affiliated entities harmless from and against all claims, suits, settlements, judgments, fines, expenses, losses, costs, deficiencies, liabilities and damages, including reasonable attorneys' fees, court costs and expenses ("**Damages**") incurred or suffered by ISL, its parent, subsidiary and affiliated entities arising out of or in connection with (i) any breach by the Customer, its employees or its sub-contractors of any of its covenants, representations, warranties, obligations or agreements made in this Agreement including breaching section 5.5 of this agreement by tendering for processing products ISL is not legally authorized to process, (ii) the processing of the Product, (iii) any claim that the Product is not sterile, (iv) any claim of personal injury, including death, or other damage arising out of the use of any of the Product, (v), the Work set forth in Schedules A, the performance or results of the Work, including Customer's use or marketing of any the Products to which the results of such Work were applied and (vi), the Work set forth in Schedules A , the processing of the Product utilizing the results, data or conclusions of such Work; except with respect to (ii), (iii) and (iv), to the extent such damages arise out of ISL's negligent acts or omissions or ISL's failure to perform the Work with respect to the Product in accordance with the parameters set forth in Schedule A.
- 8.4 *Entire Agreement.* This Agreement constitutes the final written expression of the terms of agreement between the Parties relating to the subject matter contained herein and is the complete and exclusive statement of those terms. This Agreement supersedes all prior agreements with respect to such subject matter and merges all prior discussion between the parties. All references to this Agreement shall be deemed to include the Schedule hereto. No provision in any purchase order or purchase order confirmation, whether entered into prior to, concurrently with or after the execution and delivery of this Agreement, shall be effective to the extent that provision is inconsistent with any provision of this Agreement.
- 8.5 *Amendments.* This Agreement may be amended only with the consent of both Parties hereto in writing signed by an authorized representative of each party.
- 8.6 *Severability.* The provisions of this Agreement shall be deemed severable, and the invalidity, unenforceability or illegality of any provision of this Agreement shall not in any way affect or impair the validity, enforceability or legality of the other provisions hereof.
- 8.7 *No Waiver.* The failure of either party hereto at any time to require performance by the other party of any provision of this Agreement shall in no way affect the right of such party to require performance of that provision, and any waiver by either party of any breach of any provision of this Agreement shall not be construed as a waiver of any continuing or succeeding breach of such provision, a waiver of the provision itself or a waiver of any right under this Agreement.
- 8.8 *Relationship.* Each party to this Agreement is an independent contractor, and nothing contained herein shall be construed to create an agency relationship or partnership between the parties.
- 8.9 *Force Majeure.* ISL shall not be responsible for any loss, damages or penalty resulting from any delay or damages whatsoever when such delay or damages are due to causes beyond the reasonable control of ISL, including but not limited to, labor unrest, utility interruptions, shortages, riots, insurrection, fires, flood, storm, earthquake, explosion, act of God, war, terrorism, or governmental action.
- 8.10 *Assignment.* This Agreement is not assignable by either party without the prior written consent of the other party hereto, which consent shall not be unreasonably withheld, provided, however, either party may assign its rights and delegate its obligation hereunder to an affiliate of the party or in the event of a merger, combination or sale of a party or of all or substantially all of a party's assets. For purposes of this Agreement the term "affiliate" means, with respect to a specified entity, any other person or entity which directly, or indirectly

through one or more intermediaries, controls or is controlled by or is under common control with, the entity specified.

8.11 *Schedule.* Schedule A attached to this Agreement is incorporated herein. Schedule A has additional terms and conditions which apply only to the Work referenced in that Schedule and the subject matter thereof. In the event of any conflict between the terms and conditions of Schedule A and those set forth in herein, the terms and conditions of the Schedule A shall control.

8.12 *Insurance.* Each party shall maintain at all times during the term of the Agreement, adequate insurance protecting the Products while in the party's control and, in Customer's case, while in transit to and from ISL, from any loss, casualty, or damage; provided that, ISL may self-insure for losses that arise out of ISL processing or handling.. Additionally, Customer shall maintain general liability insurance and product liability insurance resulting from use of the Products. Each insurance policy covering the risk referenced above shall be in amounts not less than \$2 million per occurrence and \$5 million in the aggregate.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective authorized representatives as of the date next to each representative's signature below.

**International Sterilization Laboratories,
LLC**

[Customer's Name]

Signature

Signature

Printed Name

Printed Name

Title

Title

217 Sampey Road

Street Address

Street Address

Groveland, Florida 34736

City, State, Zip

City, State, Zip

SCHEDULE A
EYTHLENE OXIDE PROCESSING SERVICES

Products, Price and Work Requirements for [Name of Customer]

Facility: 217 Sampey Road, Groveland, Florida 34736

Phone: (352) 429-3200; Fax: (352) 429-3269

All terms not otherwise defined in this Schedule will have the meanings given to them in the Agreement to which this Schedule is attached.

Work: Microbial reduction via Ethylene Oxide

Minimum Charge Requirements: All Work will be subject to the minimum charges set forth below. The minimum charges for *Certified Production Run* and *Sample Product Material Testing Run* may be changed at anytime. All Work charges shall be determined based upon Product specifications, processing instructions, and requirements as requested by Customer. Additional charges may apply to Product exceeding the specifications, parameters, and requirements as specified on this Schedule.

- *Certified Production Run:*

Product Specifications - Production: The processing specifications for the Product are as set forth below. Product not conforming to the description and/or processing specifications as set forth below shall be separately agreed upon in writing by the Parties.

Product Description and/or Identification Number	Processing Requirements (Cycle) #	Pallet Dimensions	Product Weight
		48" x 40"	

Processing Charge - Production: With respect to this Agreement, Customer must satisfy Minimum Volume Requirements in order to receive the following prices.

Cycle Number	Price	Volume	Effective Date
Cycle			01/01/2013
Cycle			

Provider may adjust pricing under the following conditions: In the event that there is an increase of Ethylene Oxide, Nitrogen, Energy or if a regulatory requirement prohibits PROVIDER from providing the processing services in accordance with the processing requirements set forth in Schedule A. Provider reserves the right to make the appropriate adjustments to the pricing specified in Schedule A. Nor withstanding the foregoing annual pricing adjustment shall not exceed Five (5) percent of the previous year's average processing prices.

Delivery Times – Production: Upon receipt of Product at ISL, the following must be provided, that: (i) the Products and accompanying documentation are acceptable for processing upon receipt at ISL, (ii) all purchase orders specify delivery times matching those listed on this Schedule, and (iii) with respect to the Agreement, the volume of Product to be processed is not in excess of the volume forecasted pursuant to Section 2.2 of the Agreement. Upon receiving meeting the above requirement, customers product will be placed into the schedule to be processed.

Special Product Handling : Contact Sales Department

Additional Terms and Conditions:

1. *Delivery to ISL's Facility.* All Work shall be provided at ISL's facility as set forth in this Schedule.
2. *No Devices that Store Energy.* The Customer understands that the EO processing environment is extremely combustible and requires absolute protection against any energy discharges in the EO processing chamber. Accordingly, the Customer hereby acknowledges that processing via EO is not intended for devices that store energy (such as batteries, fuel cells, chemicals that might undergo spontaneous exothermic reaction) and agrees and represents that no stored energy items or products containing such items will be submitted for EO processing without first obtaining ISL's advance written consent.
3. *Responsibilities with Respect to Product Shipped to ISL.* Customer shall ensure that the Product will assemble without overhang on 40 inch x 48 inch pallets, unless otherwise specified in this Schedule. Product not conforming to these shipment specifications shall be accepted at ISL's sole discretion. Customer will assemble the Product on pallets, unless otherwise specified in this Schedule, and the Product shall be accompanied by documents setting forth the facility from which the Product are shipped, the total number of shipping cartons and pallets in the shipment by product code and part number or catalog number, the date of the shipment and the type of Work required. Upon receipt of a shipment, ISL will complete a receiving report on the shipment. If each pallet count received is not identical to that shown on shipping papers accompanying the Product shipped by Customer, ISL shall notify Customer of such discrepancy and it shall be Customer's responsibility to locate the lost material and, if necessary, to notify the appropriate government and regulatory agencies. No Product will be processed and the provisions of Section 2.3 of the Agreement will not apply until both Parties are in agreement as to the exact count. ISL has no responsibility hereunder for verifying the product description, labeling or count. ISL is solely responsible for verifying the number of pallets received. Customer is responsible for ensuring that the product to be shipped to ISL is accurately described and labeled and that all required documentation is accurate in all respects.
4. *Records of Processing.* ISL shall assign a number to each pallet(s) of the Product. ISL will record this number, along with the name of the Product, the number of units of Product, the date on which the Work is performed, the type of Work and the chamber in which the Work was performed. Records of the Work with respect to the Product will be maintained by ISL for a period of two (2) years from the date of the Work and will be available for inspection upon request by representatives of federal or state regulatory agencies. Notwithstanding the confidentiality obligations set forth in the Agreement, Customer hereby consents to making such information available to all such representatives and agencies. Both parties will retain a copy of the Agreement for a period of two years after the last product is shipped thereunder.
5. *Compliance with Right to Know Laws.* CUSTOMER ACKNOWLEDGES THAT THE STATE OF CALIFORNIA HAS DETERMINED THAT ETHYLENE OXIDE IS A CARCINOGEN AND A REPRODUCTIVE TOXIN, AND THAT IT IS SO LISTED UNDER CALIFORNIA'S SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 ("**PROPOSITION 65**"). THE PRESENCE OF ETHYLENE OXIDE OR OTHER GAS RESIDUALS IN THE PRODUCTS FOLLOWING THE PERFORMANCE OF THE WORK MAY REQUIRE WARNING LABELS UNDER PROPOSITION 65 OR SIMILAR "RIGHT TO KNOW" LAWS IN OTHER STATES. CUSTOMER AGREES TO COMPLY WITH ANY AND ALL FEDERAL, STATE AND LOCAL LABELING REQUIREMENTS IN THIS REGARD.

Acknowledgment: ISL and Customer hereby acknowledge this Schedule A as a binding attachment to the Agreement between the Parties and warrant that the information contained herein accurately reflects Customer's processing specifications and instructions as provided to ISL by Customer for the processing of Customer's Product and ISL's charges associated with said processing. Any and all modifications or amendments to the contents of this Schedule shall be by mutual agreement and only with the written authorization of the Parties.

**International Sterilization Laboratories,
LLC**

[Customer's Name]

Signature *Date*

Signature *Date*

Printed Name

Printed Name

Title

Title

217 Sampey Road

300 Sarasota Center Boulevard

Street Address

Street Address

Groveland, Florida 34736

Sarasota, FL 34240

City, State, Zip

City, State, Zip