

## Aspen Purchase Order Terms and Conditions

### 1. Purchase Order

- a. Terms and Conditions. These Purchase Order Terms and Conditions, together with the purchase order attached hereto ("Purchase Order"), constitute the final, complete and exclusive agreement regarding the sale and purchase between Aspen Surgical Products, Inc. ("Aspen") and the recipient ("Supplier") described herein. Supplier's order confirmation or provision of any products or services pursuant to this Purchase Order constitutes irrevocable acceptance of all terms and conditions herein. Aspen objects to and is not bound by any terms or conditions in Supplier's invoice, acceptance or any other document which is inconsistent with these terms and conditions, and such are only valid if signed by an authorized representative of Aspen; provided, however, that if Aspen and Supplier are parties to a current supply agreement, quality agreement or similarly titled agreement governing the subject matter of this Purchase Order, then the terms and conditions of such agreement are incorporated herein by this reference and shall supersede these terms and conditions to the extent of any conflict.
- b. Confirmation. This Purchase Order will become a binding contract with Supplier when Supplier either confirms it or provides, in whole or in part, the products or services ordered. If Supplier fails to confirm this Purchase Order within 3 business days of receipt, it shall be deemed accepted.
- c. Changes. Aspen may make changes to this Purchase Order at any time by written notice to Supplier. If any such change causes an increase or decrease in the cost of, or the time required for Supplier's supply of, products, the parties shall meet to reach an equitable adjustment to the product price and/or delivery schedule. Any claim by Supplier for such an adjustment shall be shared with Aspen within 3 business days from the date of receipt of the written order directing the change, and no change to this Purchase Order, or adjustment to the product price and/or delivery schedule, shall be effective without Aspen's express written consent. Where the cost of raw materials made obsolete or excess as a result of an Aspen-requested change is included in the equitable adjustment, Aspen shall have the right to prescribe the manner of disposition of such raw materials.
- d. Cancellation. Aspen may at any time, without cause, cancel this Purchase Order or any portion thereof, or change the quantities or types covered by this Purchase Order at any time, provided that if (i) Aspen cancels or changes this Purchase Order after Supplier has started manufacturing the products covered by this Purchase Order, and (ii) Supplier cannot, using commercially reasonable efforts, repurpose the products for which manufacturing has begun within a reasonable amount of time (including using such products for a future Aspen order), then the parties will discuss in good faith reasonable compensation for expenses incurred by Supplier prior to such cancellation, including cost of materials.

### 2. Invoices; Payment

- a. Invoice Requirements. Supplier's invoices must (i) reference this Purchase Order number; (ii) be based on the quantity, price and other terms set forth in this Purchase Order; (iii) include a detailed identification or description of the product ordered (including item numbers, part numbers, sizes,

quantities, purchase price and extended totals); and (iv) reflect a separate line item for each additional charge, if any, including any applicable taxes, tariffs or similar fees and any approved charges for shipping, handling, expediting, etc. Aspen will not be required to pay an invoice until the invoiced products are received. Supplier warrants that each invoice will be accurate in every respect. For all costs related to payments made on Aspen's behalf to third parties, Supplier will maintain, and will provide to Aspen upon reasonable request, receipts or other supporting documentation that adequately indicate the amount and purpose of the expense. Any expense paid to or on behalf of a government official, health care professional or other person affiliated in any way with a government institution must be specifically noted as such on the invoice.

- b. Currency. Supplier will invoice Aspen in U.S. Dollars unless otherwise explicitly set forth in this Purchase Order or agreed by the parties in writing.
- c. Taxes. The prices set forth in this Purchase Order do not include any existing or future taxes or other fees. Supplier is solely responsible for filing the appropriate national, federal, state, provincial and local tax forms and paying all such taxes or fees, including income, sales, use, excise, personal property and employment taxes, tariffs, import duties and other governmental charges, due with respect to Supplier's sale and delivery of product and receipt of payment under this Purchase Order. Supplier will reasonably assist Aspen with any related government audit of Aspen. Aspen will have no responsibility to Supplier to pay or withhold from any payment to Supplier under this Purchase Order, any national, federal, state, provincial or local taxes or fees. Aspen will regularly report amounts paid to Supplier by filing the appropriate forms with the U.S. Internal Revenue Service ("IRS") and any other applicable agencies.
- d. Payment Terms. Aspen shall pay all invoices in accordance with the payment terms and any applicable early payment discounts set forth on the face of this Purchase Order.
- e. Foreign Entities. If (i) Supplier is not a U.S. incorporated entity; (ii) Supplier is providing anything other than tangible personal property (e.g. services) in the U.S.; and (iii) the Aspen entity on this Purchase Order is incorporated in the U.S., Supplier will promptly, but in any event within 10 business days, provide Aspen with an IRS Form W-8BEN, Form W-8ECI, Form W-8CE, Form W-8EXP, Form W-8IMY or Form W-9, whichever is applicable. Failure to provide the appropriate IRS form may result in withholding 35% of payments pursuant to this Purchase Order in accordance with IRS Code of 1986, as amended, and the regulations thereunder.
- f. Disputed Invoices. Aspen may return to Supplier any incomplete or incorrect invoices. Payment of invoices, including early or advance payment to secure a cash discount, does not constitute acceptance of, or waiver of dispute related to, the invoiced product or service. If Aspen disputes the accuracy of any invoice, Aspen will pay that part of the invoice that is undisputed and, after such dispute has been resolved, will promptly pay any remaining balance then due.
- g. Setoff. Aspen may set-off or otherwise withhold from invoiced amounts owed to Supplier any amounts due to Aspen by Supplier under this Purchase Order and any such

set-off amount will be treated as a "payment" under this Purchase Order.

- h. Records. Supplier will maintain records as may be necessary to adequately reflect the accuracy of Aspen's charges and invoices for reimbursement, if applicable, and maintain such other additional records as Aspen may reasonably request. Supplier will preserve such records for a minimum of 10 years after the date the last payment is made by Aspen to Supplier. Aspen and its representatives will have the right from time to time, after notice, to audit, inspect and/or verify the records kept by Supplier relating to this Purchase Order.
3. **Supply**. In the event of product shortages or back orders due to acts of God, acts of Supplier, acts of civil or military authorities or governmental priorities, strikes or other labor disturbances, acts of third party vendors or suppliers, floods, epidemics, war, riot or delays in transportation, or if for any other reason Supplier is unable to supply products pursuant to this Purchase Order, Aspen shall be a preferred customer of Supplier for delivery of whatever products remain available, and in no case will Aspen receive less than a pro rata share of such products based upon the volume ordered during the 12 month period preceding the date of this Purchase Order.

#### 4. **Delivery**

- a. Delivery Terms. All products will be delivered strictly in accordance with the delivery terms set forth on the face of this Purchase Order.
- b. Packaging. There will be no additional charge for packaging or storage before shipment of the products. Supplier will package all products in suitable containers to permit safe transportation and handling and in accordance with all instructions provided by Aspen. Each delivered container must be labeled and marked legibly to identify its contents, this Purchase Order number and product line number without opening the container, and all boxes and packages must contain packing slips listing their contents. Upon shipment of product, Supplier will provide to Aspen all shipping documents, including compliance documentation, packing sheets, delivery tickets and bills of lading, indicating this Purchase Order number, description of products, part number, revision level and quantity shipped on all packages and documents. Supplier represents and warrants that it will classify, describe, package, mark, label, provide material safety data sheets for and otherwise pack and ship the products in compliance with all laws, regulations, ordinances and orders. Material safety data sheets and labeling, if required by law, will precede each shipment, and Supplier will update them as required by law. Supplier will promptly, but in any event within 3 business days, reimburse Aspen for all expenses incurred by Aspen because of improper packing, marking, documentation or shipment.
- c. Timely Delivery. Timely delivery of all products is essential to Supplier's performance obligations. Supplier will deliver product strictly in accordance with this Purchase Order's specified (i) quantities and/or lot sizes; (ii) delivery schedule; (iii) carrier, if any; and (iv) destination. Supplier will use its best efforts to comply with any requests for urgent deliveries in a shorter time frame. Supplier will pay return shipping charges for unauthorized or untimely (either early or late) deliveries and pay for the proper disposal of excess quantities of product and for any damaged product as determined by Aspen in its sole discretion. Supplier will promptly, but in any event within 3 business days, notify Aspen verbally, with written confirmation, of any anticipated

or actual delay in making any delivery. Supplier will, at its own expense, avoid or minimize the delay to the maximum extent possible by appropriate methods, including by incurring expenditures at Supplier's expense for overtime and expedited (e.g., next day, air freight, etc.) shipment.

- d. Acceptance. Notwithstanding any prior inspections, tests or payments made by Aspen, (i) all products provided by Supplier are subject to final inspection at Aspen's facilities; and (ii) Aspen will not be deemed to have accepted any product if Aspen notifies Supplier that Aspen has rejected it within a reasonable time after such inspection.
- e. Rejection. For any product or delivery of product that is non-conforming as to quality or quantity ordered, that is damaged in any manner, that is not delivered in accordance with the specified delivery schedule, or that is manufactured, packaged, shipped, delivered or is in any way not in conformance with agreed specifications and this Purchase Order, Aspen will have the right, in its discretion, each of which will be at Supplier's risk and expense, to: (i) reject such product or revoke acceptance, in whole or in part and return such non-conforming product to Supplier; (ii) replace or correct such product; (iii) require Supplier to replace, re-work or correct such product or supply replacement parts at Supplier's, Aspen's or Aspen's customer's location, as specified by Aspen in its sole discretion; (iv) accept such non-conforming product subject to an equitable price reduction; (v) recover by offset or otherwise any and all expenses, costs and losses resulting from affected operations, price reductions and damages paid, incurred or suffered by Aspen or any of its affiliates as a result of such non-conformity; or (vi) terminate this Purchase Order or any outstanding delivery of product, without prejudice to Aspen's rights to claim damages. Supplier's expense will include the cost of transportation, handling and restocking and all expenses of unpacking, examining and repacking such product. Supplier will ship replacement product via freight prepaid at Supplier's expense, and Supplier will use expedited delivery if requested by Aspen. Aspen may inspect product by sampling. If sampling reveals defects, Aspen may elect, in its discretion, to reject the entire shipment based on such sampling or to inspect the entire shipment.

#### 5. **Products**

- a. Product Warranty. In addition to Supplier's customary warranties, express warranties associated with the products and any other warranties contained herein or required by law, Supplier hereby represents and warrants that each product, including all of its components, as of the date of receipt by Aspen (i) has not been adulterated or misbranded within the meaning of the U.S. Federal Food, Drug and Cosmetic Act; (ii) complies fully with all other applicable laws, regulations and governmental rules; (iii) is free from all liens, claims and encumbrances, except to the extent arising directly out of Supplier's right to payment therefor; (iv) will not infringe or contribute in any way to the infringement of any intellectual property right of Supplier or its representatives or any third parties, regardless of whether such are used, sold or combined with other components or products or included in an Aspen product, and Aspen may use and disclose any products provided pursuant to this Purchase Order without restriction for any purpose, including to make, develop, use, market, offer for sale, sell and commercialize any product or service without restriction of any intellectual property right of Supplier or its

representatives or any third party that may cover such products; (v) will conform in all material respects to the requirements of this Purchase Order, as well as to any specifications, drawings, samples or other descriptions referenced in this Purchase Order or provided by Aspen or at Aspen's instruction; (vi) will be fit, sufficient and suitable for the particular purpose for which Aspen intends to use the product, including the specified performance in the component, system, subsystem and product location and the environment in which it is or may be reasonably expected to perform; and (vii) will be merchantable, of good material and workmanship and free from any defect for the period equal to the life of the product. The foregoing representations and warranties shall survive inspection, acceptance of and payment for the products and shall run to Aspen and its successors, assigns and customers and to the purchasers and end users of each such product (or any product or item into which such product is incorporated). Supplier hereby assigns to Aspen all rights under all warranties and guarantees of any of its suppliers as related to the products.

- b. Non-Conformance with Product Warranty. If Aspen receives a complaint or otherwise becomes aware that a product fails to conform to the warranties set forth herein or any other warranty approved by Supplier in writing, Aspen will notify Supplier of such non-conformance, and Supplier will, at Aspen's sole option, either (i) refund the full purchase price; or (ii) repair or replace the product free of charge. Supplier acknowledges that Aspen has an obligation to service its customers and therefore, Aspen may choose to replace the non-conforming product with a substitute product at its sole discretion and without input from Supplier, and in such event Supplier will be responsible for any out of pocket costs incurred by Aspen in connection therewith, including the cost of procuring such product from another source. Such replacement will not relieve Supplier of any of its obligations hereunder. Each party will assist and cooperate with the other party regarding any and all product warranty non-conformances. Supplier agrees that it will not contact Aspen customers directly, and if an Aspen customer contacts Supplier directly in order to report a warranty claim, request a repair or replacement part or make another inquiry, Supplier will promptly instruct such customer to contact Aspen directly.
- c. Quality System. Supplier will maintain a formal quality system that meets Aspen's quality system requirements, including appropriate controls on design, production, sourcing, inspection, testing, lot traceability, shipping, service, repair, documentation, record keeping and corrective and preventive action to address defects in the products and underlying processes, and that ensures that each product provided to Aspen meets the specifications for that product. In addition, Supplier will comply with the quality and other requirements in the Quality Agreement set forth in Attachment 1 hereto, which is hereby incorporated into and made a part of this Purchase Order and which shall prevail over these terms and conditions to the extent of any conflict.
- d. Certificates of Origin. Upon request, Supplier will immediately provide to Aspen all certificates of origin or domestic value-added and all other information relating to the costs and places of origin of the products or the services and the materials contained therein or used in the performance thereof, as may be requested by Aspen to comply fully with all customs, tariffs and other applicable

governmental regulations. Any change which may change the country of origin of a product will be deemed a change requiring official notice. Supplier will comply strictly with any country of origin specifications for the products.

- e. Intellectual Property.
  - i. Supplier covenants and warrants that it imposes no post-sale restrictions relative to any product provided to Aspen. The parties acknowledge and agree that except as otherwise set forth herein or unless otherwise agreed in writing: (1) all intellectual property disclosed, supplied, incorporated or otherwise used in connection with this Purchase Order shall remain the property of the party (or its licensor) which owns such intellectual property, and any inventions and developments derived therefrom are and shall remain the property of the owner (or its licensor) of such intellectual property; (2) nothing in this Purchase Order shall be construed as conferring any license or granting any rights in favor of either party in relation to such intellectual property rights (other than as is necessary in relation to the use, lease, loan, maintenance, importation, modification, repair, testing, transfer or sale of the products by Aspen and its customers); and (3) any reputation in any trademarks affixed or applied to the products or their packaging shall accrue to the sole benefit of the owner (or its licensor) of such trademarks. Other than pursuant to this Purchase Order or as otherwise agreed in writing, neither party shall use or seek to register any trademark or trade name (including any company name) which is identical to, confusingly similar to or incorporates any trademark or trade name which the other party or any of such other party's affiliates owns or claims rights to in anywhere in the world. If at any time it is alleged that a product infringes the rights of any third party or if, in Aspen's reasonable opinion, such an allegation is likely to be made, Supplier shall at its own cost either modify or replace the affected products in order to avoid the infringement, procure for Aspen the right to continue using the products or repurchase the products at the purchase price paid by Aspen. Each party shall promptly and fully notify the other party of any actual, threatened or suspected infringement of any intellectual property rights in the products which comes to such party's notice and any claim by any third party that comes to such party's notice that the sale or advertisement of the products infringes the rights of any person.
  - ii. If Aspen specifies in writing that Supplier is engaged to manufacture finished goods ("Finished Products") utilizing, in whole or in part, an Aspen-owned or -licensed patent (an "Aspen Patent"), Aspen hereby grants to Supplier a limited, non-exclusive, worldwide, non-transferable, non-sublicensable, royalty-free, fully paid-up right and license under such Aspen Patent to make, use, offer to sell, sell and import such Finished Products solely in connection with Supplier's manufacture and supply of the Finished Products for Aspen pursuant to this Purchase Order, which license Aspen may revoke at any time with or without notice. If Aspen specifies in writing that Supplier is engaged to manufacture Finished Products to be branded and/or packaged utilizing specific Aspen-owned or -licensed trademarks (the "Aspen Trademarks"), Aspen hereby grants to Supplier a limited, non-exclusive, worldwide, non-transferable, non-sublicensable, royalty-free, fully paid-up right and

license under such Aspen Trademarks solely in connection with Supplier's branding and packaging of such Finished Products for Aspen pursuant to this Purchase Order, which license Aspen may revoke at any time with or without notice. The Aspen Patents and Aspen Trademarks (collectively, the "Aspen IP") and all associated goodwill and rights arising from the use thereof will remain the sole and exclusive property of Aspen at all times. Supplier specifically agrees that it will not at any time use the Aspen Trademarks, or any trademarks or names confusingly similar thereto, on production or manufacture of any other products for any third parties. Supplier agrees that it has no right of any kind to sell, resell or to otherwise dispose of any products bearing the Aspen Trademarks to any third parties at any time. Supplier is absolutely prohibited from using any of the Aspen Trademarks, and from using any names or trademarks confusingly similar thereto, other than in connection with its provision of products pursuant to this Purchase Order in strict accordance with the terms and conditions hereof. As between Supplier and Aspen, Aspen shall own the intellectual property rights in and to the Finished Products, including the Aspen IP, and any innovation or improvement made by either Supplier or Aspen or by third parties subcontracted by Supplier related to the Finished Products and/or the Aspen IP shall be the sole and exclusive property of Aspen. As a condition of the grant of the license rights in this section, Supplier will, at all times, adhere to its obligations hereunder. In addition, Supplier will observe the same quality and control standards as are specified by Aspen, and Aspen will have the right to monitor Supplier's compliance with such obligations and quality control standards at all times.

- f. Supplier's Breach. If Supplier breaches the terms or conditions of this Purchase Order for any reason whatsoever, Supplier hereby grants to Aspen a worldwide, transferable, sub-licensable right and license, under any and all intellectual property rights related to the product(s) remaining with Supplier that are necessary (if any) to manufacture, have manufactured, use, import, market, reconstruct, offer for sale and sell the products and modifications thereof, in quantities and for a time reasonably required to mitigate the effects of such breach. For the licenses granted by Supplier under this Purchase Order, Aspen will pay a fee which is part of and reflected in the purchase price of each of the products provided to Aspen by Supplier.
- g. Aspen Property. If Supplier is to produce product in accordance with designs, specifications or drawings provided by Aspen, or if Aspen pays for or provides to Supplier any equipment, supplies, tools, tooling or other property in connection with or used in the performance of this Purchase Order ("Aspen Property"), Aspen will own all right, title and interest in and to such Aspen Property, and Supplier will (i) hold such Aspen Property in confidence; (ii) mark such Aspen Property in a manner that reflects that it belongs to Aspen; (iii) store such Aspen Property apart from Supplier's other property; (iv) not move the Aspen Property to any location other than the site approved by Aspen without the prior written consent of Aspen; (v) not sell, lease, mortgage or otherwise encumber or dispose of any Aspen Property; (vi) be responsible for the risk of loss, repair or replacement of the Aspen Property, and for keeping it in

good working condition; and (vii) return such Aspen Property, at Supplier's expense, to Aspen in good condition, subject to normal wear and tear, at Aspen's request or when the Aspen Property is no longer used by Supplier or upon the termination or completion of this Purchase Order. Supplier will use the Aspen Property exclusively for the benefit of Aspen. Aspen may, upon not less than 1 day's notice, enter Supplier's premises during regular business hours and take possession of any or all of the Aspen Property.

**6. Additional Representations, Warranties and Covenants.**

- Supplier represents and warrants to Aspen, its affiliates and their respective customers, and any subsequent owners, operators or recipients of the product, that:
- a. It is duly organized and validly existing under the laws of its jurisdiction of organization, has the legal capacity and right to enter into this Purchase Order, has the authority to conduct the business in which it is currently engaged and has not made, and will not make, any contract or commitment contrary to the terms of this Purchase Order or in derogation of any intellectual property rights acquired or to be acquired hereunder by Aspen.
- b. Unless otherwise expressly stated on the face of this Purchase Order, the products are manufactured entirely with new materials and none of the products are, in whole or any part, governmental or commercial surplus or used, remanufactured, reconditioned or of such age or condition to impair its fitness, usefulness or safety.
- c. It acknowledges that certain products manufactured and/or distributed by Aspen are intended for worldwide distribution and must comply with applicable international environmental requirements, such as the European Union's Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation and Authorization of Chemicals ("EU REACH") and the European Union's Directive on the Restriction of Hazardous Substances (Directive 2011/65/EU) ("EU RoHS 2"). To the extent applicable, Supplier represents and warrants that the products provided by Supplier to Aspen comply with the latest revisions/updates of all applicable international environmental laws, rules, regulations and standards including the requirements of EU REACH and EU RoHS 2 and do not contain any chemicals over the allowed limit dictated by these laws, enabling Aspen to distribute them on a worldwide basis without restrictions. Supplier will notify Aspen if Supplier determines any product provided to Aspen is out of compliance. Supplier will take all actions and deliver all information requested by Aspen regarding such regulations and standards.
- d. It will conduct all employment and other activities related to this Purchase Order in compliance with the standards of integrity and human rights set out in Aspen's third party code of conduct (available to Supplier upon request) and the Ethical Trading Initiative Base Code (available at <https://www.ethicaltrade.org/resources/eti-base-code>); in particular, prohibitions on forced and child labor, excessive working hours, discrimination, harassment and other harsh or inhumane treatment, and their standards related to freedom of association and collective bargaining, safe and hygienic working conditions and living wages. Supplier agrees to hold its suppliers and other third parties to the same standards when performing its obligations under this Purchase Order and to ensure that it has human rights policies and a means of raising complaints to address any breaches of such policies. Aspen and its representatives will



have the right, directly or through an independent agent, to conduct due diligence surveys and audits, staffed as Aspen deems appropriate, to verify Supplier's past and current compliance with this section, and Supplier will cooperate fully and respond in a timely manner and in good faith, including making relevant documents and personnel available, to facilitate any such due diligence surveys or audits.

- e. It and the products shall comply with the requirements of all applicable laws, rules, orders, and regulations of governmental authorities, including, but not limited to: (i) Executive Orders 11246 and 13496 of the President of the United States; the equal opportunity clause set forth in 41 C.F.R. § 60-1.4(a), which regulation bars discrimination against all individuals based on their race, color, sex (including pregnancy, gender identity, and sexual orientation), religion, national origin, age (40 or older), disability, or genetic information; the prohibition of segregated facilities set forth at 48 C.F.R. § 52.222-21(b); and the employee notice set forth at 29 C.F.R. Part 471, Appendix A to Subpart A; all of which are incorporated herein by reference; (ii) 41 C.F.R. §§ 60-300.5(a) and 60-741.5(a) prohibiting discrimination against qualified individuals on the basis of protected veteran status or disability, and requiring affirmative action by covered prime contractors and subcontractors to employ and advance in employment qualified protected veterans and individuals with disabilities; and (iii) to the extent the U.S. government is an end user of the product, the prohibition on contracting for hardware, software, and services developed or provided by Kaspersky Lab and other covered entities set forth at 48 C.F.R. § 52.204-23, which regulation bars contractors and subcontractors from providing to the U.S. government any part, component, service or other product that contains any hardware, software or service that is developed, in whole or in part, or provided by (a) Kaspersky Lab, (b) any successor entity to Kaspersky Lab, (c) any entity that controls, is controlled by or under common control with Kaspersky Lab, or (d) any entity of which Kaspersky Lab has a majority ownership ((a)-(d) collectively, "Covered Articles"). Supplier shall not use any Covered Article in the development of data or deliverables for Aspen. To the extent Supplier identifies a Covered Article that is or has been provided to Aspen, Supplier shall immediately and not later than 24 hours from the date of identification or notification, report, in writing, to Aspen: Supplier name, brand, model number, manufacturer part number, or wholesaler number, item description and any readily available information about mitigation actions undertaken or recommended. Supplier will provide additional information as required by the regulation and/or requested by Aspen.
- f. Supplier will provide Aspen with all information requested by Aspen related to the use of any Conflict Minerals that originate in the Democratic Republic of the Congo or any of its surrounding countries in any products. "Conflict Minerals" means gold, tin, tantalum and tungsten and any additional minerals added to Section 1502 of the Dodd Frank Act.
- g. All of Supplier's representations and warranties set forth herein will survive any delivery, inspection, acceptance or payment by Aspen of or for any product and will be enforceable by Aspen on its own behalf and on behalf of Aspen's customers and any subsequent owners, operators or recipients of the product and will not be deemed to be exclusive of any other remedy at law or in equity available to

Aspen, its customers or any other owners, operators or recipients of the product.

- 7. **Confidentiality.** Aspen retains all rights in designs, equipment, drawings, specifications, financial information, pricing information, marketing plans, production plans, manufacturing processes, reports and any and all other confidential and/or proprietary information furnished to Supplier ("Confidential Information"), and such information shall remain the sole property of Aspen. Supplier agrees not to use and/or disclose Confidential Information except as permitted herein. Supplier shall use all reasonable care, but in no event less than the same degree of care that it uses to protect its own confidential information of similar importance, to prevent the unauthorized use, disclosure, publication or dissemination of the Confidential Information. Supplier shall restrict access to the Confidential Information (and any concepts, invention or other information derived therefrom) to only those of its employees, employees of subsidiaries or related corporate entities, and representatives or advisors to whom such access is reasonably necessary or appropriate for carrying out the permitted use of such confidential information. Supplier shall return all Confidential Information to Aspen upon Aspen's request or upon completion of all services performed by Supplier for Aspen. Supplier will not use Aspen's name or logo in any public or marketing manner or disclose to other parties the fact that Aspen has purchased or plans to purchase product from Supplier, without Aspen's prior written consent, or unless required by law or as part of a legal proceeding related to this Purchase Order.
- 8. **Insurance.** Supplier will provide to Aspen a certificate(s) of insurance before any products are delivered or services are performed. Supplier will maintain Commercial General Liability insurance which includes products/completed operations liability, contractual liability, personal injury liability and broad form property damage coverage with limits of at least US\$ 10,000,000 per occurrence. Such limits may be satisfied by a combination of primary and umbrella/excess liability policies. Such coverage must include worldwide coverage territory, including the U.S. and Canada, and must name Aspen as an additional insured. Supplier will maintain Cyber Liability insurance, which coverage shall include but shall not be limited to claims involving loss or disclosure of Confidential Information or personal health information, breach of privacy, information theft, alteration of electronic information, extortion, unauthorized use of or access to computer systems, and network security, and shall also include coverage for breach response costs, regulatory fines and penalties, and credit monitoring, with limits of at least US\$ 5,000,000 per occurrence. Such coverage must include worldwide coverage territory, including the U.S. and Canada, and must name Aspen as an additional insured. Supplier will maintain Workers Compensation insurance in the state in which any services are being performed and must evidence a limit of liability for Employers Liability of not less than US\$ 1,000,000 per accident. Such coverage will include a waiver of subrogation in favor of Aspen. If Supplier brings vehicles onto Aspen's or Aspen's customers' premises, Supplier will maintain insurance covering any owned, non-owned or hired vehicles with limits of at least US\$ 1,000,000 per occurrence combined single limit bodily injury and property damage. If Supplier is providing professional services (e.g., engineering, design, software/programming, etc.), Supplier will maintain Professional Liability (Errors & Omissions) insurance for a limit of liability of not less than US\$ 2,000,000 per loss. Such coverage must include worldwide coverage territory, including the U.S. and Canada. Insurance evidenced above will be

primary and not entitled to contribution from any insurance maintained by Aspen or any of its Affiliates. If Supplier employs any subcontractors, Supplier will require that the subcontractors carry the same coverages in the same limits as set out in this section.

## 9. Indemnification; Limitation of Liability

- a. Indemnification By Supplier. Supplier will indemnify, defend and hold harmless Aspen and its affiliates, shareholders, employees, officers, directors, agents, suppliers and representatives from and against any and all claims, actions, damages, costs, losses, expenses (including legal costs and expenses), penalties, fines, obligations and liabilities of any kind (including damage to the environment) (collectively, "Losses") relating to or arising out of (i) Supplier's negligence, bad faith or willful misconduct; (ii) Supplier's breach of any representation, warranty or covenant herein; (iii) violations of law by Supplier in the performance of this Purchase Order or while entering, being present at or leaving Aspen's or Aspen's customers' property; (iv) any claim or litigation which asserts or is based upon any alleged design (except to the extent of Aspen's responsibility for the design) or manufacturing defect, negligence, professional liability, error or omission, willful misconduct, failure to warn or breach of warranty relating to Supplier products (including parts and components thereof purchased by Supplier from its suppliers) purchased by Aspen; or (v) any infringement of intellectual property rights relating to a product or component thereof (whether by the product or component thereof alone or in combination or use with other products or components).
- b. Indemnification By Aspen. Aspen will indemnify, defend and hold harmless Supplier from and against any and all third party Losses relating to or arising out of (i) Aspen's gross negligence, bad faith or willful misconduct; or (ii) violations of law by Aspen in the performance of this Purchase Order.
- c. Limitation of Liability. IN NO EVENT SHALL ASPEN AND/OR ANY AFFILIATE OF ASPEN BE LIABLE TO SUPPLIER FOR ANY EXEMPLARY, INCIDENTAL, INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING WITHOUT LIMITATION LOSS OF PROFIT, LOSS OF USE, SAVINGS OR REVENUE, WHETHER OR NOT ASPEN AND/OR ANY AFFILIATE OF ASPEN HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING OUT OF THIS PURCHASE ORDER OR THE RELATIONSHIP OF SUPPLIER AND ASPEN.

## 10. Compliance

- a. Compliance Requirements
  - i. Debarment. Supplier represents and warrants that Supplier and its directors, officers and employees have not been, and are not currently, excluded, debarred, or otherwise made ineligible to participate in any "Federal health care program" (as defined at 42 U.S.C. § 1320a-7b(f)) or any Federal procurement or non-procurement program (the "Federal Programs"). Supplier further represents and warrants that Supplier and its directors, officers and employees (1) have not been convicted of a criminal offense related to the provision of health care items or services, and (2) are not under investigation or otherwise aware of any circumstances which may result in Supplier being excluded from participation in any Federal Programs. Supplier will immediately notify Aspen, in writing, of any change in the status of the

representations and warranty set forth in this section.

- ii. Anti-Corruption. Supplier represents and warrants that it has complied and will comply with all applicable anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, and that it has not made, offered or authorized and will not make, offer or authorize any payment, gift, promise or other benefit, whether directly or through any other person or entity, to any "government official" (i.e., any official or employee of any government, or any department, agency or instrumentality thereof, including any person employed by or acting on behalf of a public agency, government-controlled enterprise or public international organization, or any political party, political official or candidate for political office), health care professional, any immediate family member of a "government official" or health care professional (i.e. spouse, parent, child, sibling, sibling's spouse or financial dependent) or any other person or organization for purposes of influencing official actions or decisions or securing any improper advantage in order to obtain or retain business. Except as otherwise disclosed in writing to Aspen, no "government official" or immediate family member of a "government official" is or will become associated with, or presently owns or will own any interest in Supplier.
- iii. Inquiries by Government Authority. Supplier represents and warrants that it has not received any notice, subpoena, demand or other communication (whether oral or written) from any governmental authority at any time in the last 5 years regarding Supplier's actual, alleged, possible or potential violation of, or failure to comply with, any laws, regulations or industry codes governing bribery, money laundering or other corrupt practices or behavior.
- iv. Aspen Due Diligence. Aspen will be entitled to conduct regular due diligence surveys and audits, staffed as Aspen deems appropriate, and at Aspen's own cost and expense, to verify Supplier's past and current compliance with the anti-corruption laws of any relevant jurisdiction, Aspen's third party code of conduct and Supplier's obligations under this section. Supplier will cooperate fully and respond in a timely manner and in good faith, including making relevant documents and personnel available, to facilitate any such due diligence surveys or audits.
- v. Supplier understands that products and services provided under this Purchase Order are subject to compliance with U.S. and any other applicable export laws, including but not limited to any local laws, the Export Administration Regulations ("EAR"), the anti-boycott and embargo regulations and guidelines issued under the EAR, the anti-boycott provisions of the Internal Revenue Code, the International Traffic in Arms Regulations ("ITAR") and the various sanctions regulations and authorizations implemented by the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"). Supplier agrees to abide by any restrictions or conditions respecting the export, re-export or other transfer of the deliverables that are in effect now or are hereafter imposed by the U.S. Government, and will not export, re-export, transfer or otherwise release, export, disclose, furnish or otherwise provide any article, technical data, technology, defense service, or technical assistance to any foreign person or entity, whether within

the U.S. or abroad, without obtaining in advance any necessary export authorizations, licenses or other approvals from applicable governmental authorities. Supplier further agrees to determine whether it is, and represents that it is not, owned directly, indirectly, or in the aggregate 50% or more by Specially Designated Nationals ("SDNs") or parties designated on Sectoral Sanctions Identifications Lists ("SSIs") or Foreign Sanctions Evaders List ("FSEs") under Executive Orders of the President of the United States or the regulations of OFAC. Supplier agrees to inform Aspen of any changes in its ownership structure that will cause it to be 50% or more owned by SDNs, SSIs or FSEs. Aspen will be entitled to conduct regular due diligence surveys and audits, staffed as Aspen deems appropriate, and at Aspen's own cost and expense, to verify Supplier's past and current compliance with all applicable export controls and economic sanctions laws and Aspen's third party code of conduct. Supplier will cooperate fully and respond in a timely manner and in good faith, including making relevant documents and personnel available, to facilitate any such due diligence surveys or audits. Nothing herein is intended to amend, waive or supersede any of the requirements applicable to Supplier under applicable export controls and economic sanctions laws.

- vi. Supplier will require any subcontractors or other persons or entities that provide products or services to Supplier pursuant to this Purchase Order to agree to and abide by the representations and warranties in this section.
- vii. Periodically, as requested by Aspen, Supplier will cause one of its authorized officers to execute and deliver to Aspen a Certificate of Ethical Practices that confirms Supplier's continued compliance with the provisions of this section.
- viii. Supplier will promptly notify Aspen of (1) the occurrence of any fact or event that would render any representation, warranty, covenant or undertaking in this section incorrect or misleading, (2) any notice, subpoena, demand or other communication (whether oral or written) from any governmental authority regarding Supplier's actual, alleged, possible or potential violation of, or failure to comply with, any laws or regulations governing bribery, money laundering or other corrupt payments, or any export laws, and (3) any governmental investigation, audit, suit or proceeding (whether civil, criminal or administrative) regarding Supplier's violation of, or failure to comply with, any such laws or regulations.
- ix. Supplier will cooperate fully with Aspen regarding the investigation of any allegation, event, fact or occurrence which calls into question Supplier's compliance with any representation, warranty, or covenant in this section. If requested by Aspen, Supplier will (1) appoint an executive with sufficient seniority and authority to respond to requests from Aspen, and (2) promptly provide such records and information, and provide access to such of its employees, contractors and consultants, as may be reasonably requested by Aspen regarding any such investigation.
- x. Periodically, as requested by Aspen, Supplier will provide Aspen the names of its employees and representatives who will interact with health care professionals and government officials on behalf of

Aspen, as well as certain other employees specified by Aspen, and will cause such employees to undertake compliance training in a form approved by Aspen.

- xi. Supplier will designate a compliance officer to oversee and ensure Supplier's compliance with its obligations under this section. The compliance officer will be of sufficient seniority, and will be provided with sufficient resources, to fulfill his or her obligations under this section.
- xii. Supplier will indemnify and hold Aspen harmless from and against any liability claims, demands or expenses (including attorney's or other professional fees) arising from or relating to Supplier's noncompliance with the terms of the anti-corruption and export controls and sanctions clauses of these terms and conditions.
- xiii. Notwithstanding anything to the contrary herein, Aspen may, in addition to its other remedies, immediately terminate this Purchase Order if Aspen should receive information which it determines in its sole discretion to be evidence of a breach by Supplier of any representation or warranty set forth in this section. In the event of such termination, Aspen will have no liability to Supplier for any fees, reimbursements or other compensation under this Purchase Order, including for services previously performed.

#### **11. Miscellaneous**

- a. Conflicts of Interest. Neither Supplier nor any subcontractor or agent of Supplier will: (i) pay any amounts in any form to any employee of Aspen or any of his or her designees; or (ii) favor any employee of Aspen, or any of his or her designees, with gifts or entertainment of significant cost or value, or with services or goods sold at less than full market value. Supplier will notify Aspen immediately upon becoming aware of any other conflicts of interest that may exist from time to time between Supplier, its subcontractors or any of their respective employees, and Aspen. If Aspen becomes aware of any such conflict of interest, Aspen may request that such employee not be involved, directly or indirectly, in the work contemplated by this Purchase Order, and Supplier will honor such request.
- b. Independent Contractor. Supplier is an independent contractor and nothing herein will create, or be construed to create, any agency, partnership, joint venture or other form of joint enterprise between Supplier and Aspen. Supplier has no authority to make any agreement or commitment, or to undertake or incur any obligation or liability on behalf of Aspen or any of its affiliates, except as otherwise expressly authorized in writing by Aspen.
- c. Assignment; Third Party Beneficiaries. Supplier may not assign, delegate or otherwise transfer this Purchase Order or any of its obligations hereunder without Aspen's prior written consent. Any attempted assignment or transfer will be null and void. The rights and obligations of the parties to this Purchase Order will inure to the benefit of and will be binding upon the successors and permitted assigns of each party. Aspen's parent, subsidiaries and affiliates (each a "Beneficiary") will be third party beneficiaries under this Purchase Order to the extent the products provided hereunder impact a Beneficiary, and any such Beneficiary will have the right to enforce this Purchase Order as if it were a party hereto.
- d. Notices. Communications regarding orders may be sent by local mail, electronically transmitted or faxed. All amendments and official notices required hereunder will be

in writing to the addresses listed on the face of this Purchase Order and will be considered given (i) when delivered personally; (ii) when sent by commercial express carrier; or (iii) 3 calendar days after having been sent, postage prepaid, by registered mail.

- e. Governing Law. Any matters relating to this Purchase Order shall be governed and construed in accordance with the laws of the State of Michigan, USA, without regard to any applicable conflicts of law. The application of the United Nations Convention on Contracts for the International Sale of Goods is expressly excluded.
- f. Venue. If Supplier is in the U.S., each party (i) will bring disputes, claims and actions in a U.S. state court sitting in Michigan or Federal court in the Western District of Michigan; and (ii) submits to the jurisdiction of any and all of the courts identified in (i), together with their respective appellate courts. If Supplier is outside of the U.S., then (iii) any dispute relating to this Purchase Order, including the breach, termination or validity thereof, will be finally resolved by arbitration in the English language, in accordance with the International Institute for Conflict Prevention & Resolution Rules for Non-Administered Arbitration currently in effect at the time of the dispute; (iv) each party will designate one arbitrator and the sole responsibility of the party-designated arbitrators will be to appoint a third, neutral arbitrator; (v) such third arbitrator will be the sole arbitrator of the dispute; (vi) the arbitration will be governed by the U.S. Federal Arbitration Act, 9 U.S.C. §§1 et seq.; (vii) the

arbitrator will follow the governing law provisions of these terms and conditions; and (viii) judgment upon the award rendered by the arbitrator may be entered by any court having jurisdiction thereof. The place of arbitration will be Grand Rapids, Michigan. The foregoing is without prejudice to the right of Aspen to (ix) bring suit against Supplier with the competent court where Supplier has its registered office or place of business; and (x) bring suit and seek relief at any court in connection with seeking injunctive relief. Each party waives its right to a jury trial and for a retrial in the local court when a local enforcement order is sought.

- g. Waiver. Either party's failure to enforce any of the provisions herein will not be construed as a waiver of such provisions. Either party's waiver of any of its remedies for a breach of any of the provisions herein is without prejudice and will not operate to waive any other remedies that the non-breaching party will have available to it at law or in equity, nor will it waive the non-breaching party's rights to any remedies for a future breach.
- h. Severability. If a court of competent jurisdiction finds any provision herein void or unenforceable, such findings will not be construed to render any other provision either void or unenforceable, and all other provisions will remain in full force and effect.
- i. Survival of Covenants. Any provision of this Purchase Order which contemplates performance or observance following its termination or completion will survive such termination or completion.



## Attachment 1

### Quality Agreement

**1. Legal Requirements.** Supplier agrees to comply with all applicable legal and regulatory requirements that apply to the products that are medical devices or products that are components that go into a medical device, including regulations promulgated by the U.S. Food and Drug Administration (the "FDA") under the Federal Food, Drug, & Cosmetic Act as amended from time to time at Title 21, Chapter 9 of the U.S. Code, 21 U.S.C. §§ 301–399a and Title 21 of the U.S. Code of Federal Regulations Part 820 (the "Legal Requirements").

**2. Authorizations.** As applicable, Supplier has obtained or made and will maintain all licenses, permits, registrations, authorizations and submissions as are necessary to perform Supplier's services and to manufacture and sell the product. Supplier will provide copies of such licenses, permits, registrations, authorizations and submissions to Aspen upon request.

**3. Product Changes.** Supplier will manufacture the product in accordance with this Quality Agreement (this "Agreement"), the applicable Legal Requirements, the specifications, and any applicable regulatory approval, marketing clearance or other marketing authorization. Supplier acknowledges that modifications to products may affect the performance or regulatory status of other products into which the products are incorporated, and that modifications to any product provided pursuant to this Agreement (whether a finished product or a part, component, or subassembly) are strictly subject to this and other modification provisions. Supplier will not implement any such modification unless and until it receives written acceptance of such modification by Aspen in the form of an approved change order. Supplier implementing any such modifications without proper approval will be subject to financial penalties. Supplier will maintain a formal process to document changes to Supplier's policies, procedures, operations and the specifications and will evaluate all proposed changes to the products with regard to potential impact on the products' safety, efficacy, performance and intended use(s).

**4. Supplier Evaluation.** Supplier will establish and maintain quality requirements that must be met by suppliers and contractors to ensure that all purchased products and services conform to specified requirements. Supplier will monitor the performance of suppliers supplying materials for use in the products. To the extent Supplier subcontracts any product manufacturing or services provided to Aspen, Supplier will ensure that such subcontractor(s) are bound by this Agreement.

#### **5. Manufacturing Standards; Quality Assurance**

**5.1. Manufacturing and Quality Records.** Supplier will maintain complete and accurate manufacturing and quality records for the products in accordance with Legal Requirements, including as applicable product master records, product history records, master production and control records, batch production and control records, and laboratory records. Supplier will retain such records in accordance with Legal Requirements. Such records will be made available to Aspen upon request.

**5.2. Incoming Inspections.** Supplier is responsible for the identification, sampling, testing and approval of any incoming materials, components and packaging materials used in the manufacture of the products in accordance with Legal Requirements. All sampling and testing will become part of the

batch records and will be reviewed by Supplier's quality assurance department before release of the product. Supplier will make inspection documentation available to Aspen upon request. Documentation must be provided at the time of receipt of the related product by Aspen. Documentation will be included with shipment and emailed to [SQACerts@aspensurgical.com](mailto:SQACerts@aspensurgical.com).

**5.3. Material Control and Traceability.** All materials and components used in the manufacturing, assembling and packaging of the products will be stored and handled in accordance with Legal Requirements. Materials used to manufacture the products must be controlled, identified by lot number and traceable.

**5.4. Verification and Validation.** Supplier will ensure that its manufacturing processes and equipment are appropriately verified and validated as required by Legal Requirements. Verification, validation, equipment calibration and equipment validation data will be documented and made available to Aspen upon request.

**5.5. Quality Control.** Supplier will verify that the products are manufactured, tested and stored in accordance with the specific processes and methods specified in applicable Legal Requirements and the specifications and otherwise comply with the representations and warranties given by Supplier in this Agreement.

**5.6. Certificate of Analysis/Batch Records.** When requested by Aspen, Supplier will complete and send with each shipment of product a "Certificate of Compliance" and full batch records certifying that each product was: (a) manufactured according to Supplier's procedures and in compliance with applicable Legal Requirements; and (b) tested and confirmed to meet all specifications. Each Certificate of Compliance will be signed and dated by a duly authorized official of Supplier's quality control or quality assurance department.

**5.7. Non-conforming Products.** Supplier will control and physically segregate all non-conforming products, or any material considered unacceptable for use in the manufacture of products, from conforming products and approved material in accordance with Legal Requirements. Supplier will immediately notify Aspen of any non-conforming product that was released for shipment to Aspen or Aspen's designee(s) or customers and will provide Aspen with all investigation reports, quality reports or other means of reporting Supplier's investigation process. For non-conforming products that were released, Supplier, in consultation with Aspen, will decide whether non-conforming products should be destroyed or returned to Supplier. Supplier will pay all expenses related to destroying or returning the products. At Aspen's sole discretion, without prejudice to Aspen's rights, Aspen may cancel any order or payment covering non-conforming products or may elect to have Supplier replace the non-conforming product(s), and Supplier will pay all expenses related to such replacement.

**5.8. Product Quality Issues.** Aspen will notify Supplier of any problems isolated as Supplier defects that are found during the use or distribution of the product. When requested by Aspen, Supplier will promptly investigate the identified issue(s) within timeframes established by Aspen. Supplier will provide timely updates and completed investigation reports to Aspen as reasonably requested. When the need for a corrective action has been identified, Supplier will investigate appropriately,

determine root cause, develop an action plan to address the problem, implement proposed corrections, evaluate and determine effectiveness in accordance with applicable Legal Requirements and Supplier's quality system.

**6. Post-market Reports.** Aspen may be responsible for preparing a periodic post-market report (e.g., annual report required by regulatory standards). Promptly, upon Aspen's request, Supplier will provide to Aspen in writing any data required for submission of any post-market or annual report.

**7. Labeling and Packaging.** Supplier will label and package products in accordance with applicable Legal Requirements and specifications and will include a unique identifying lot number.

**8. Compliance Deficiencies.** Should Supplier become aware of any issue that could affect the quality, safety, identity, efficacy or regulatory compliance of product (whether or not already shipped and/or distributed), Supplier will immediately notify Aspen in writing (but in any event, no later than twenty-four (24) hours after the discovery of such issue). If Supplier becomes aware of any safety, quality or efficacy issues relating to the products, Supplier will (a) immediately inform Aspen of the same; (b) contain and segregate any affected product on Supplier's premises; (c) initiate corrective actions; and (d) periodically update Aspen regarding the status of the same, including upon Aspen's request.

**9. Regulatory Authority Communications and Investigations.** Supplier will promptly notify Aspen in writing of any regulatory authority communications, actions or inquiries that relate to the products, whether oral or written, of which Supplier receives or becomes aware. Supplier will promptly provide Aspen with copies of any documentation relating to same. If necessary, Supplier may redact names of other customers or products to protect confidentiality. In the event of an investigation or inspection of Supplier by regulatory authorities, Supplier will notify Aspen within two (2) business days prior to any such inspection, or if prior notice is not possible, Supplier will notify Aspen immediately after learning of such inspection. Supplier will promptly provide Aspen with copies of all documentation relating to such inspection and Supplier's response(s). Supplier will immediately notify Aspen in writing if Supplier becomes aware of any regulatory authority investigations related to a recall, field alert, stock recovery, product withdrawal, field correction or other similar corrective action (each a "Recall") or other corrective actions relating to the products.

**10. Product Complaints.** Supplier will collect, investigate and timely respond to complaints or inquiries from Aspen relating to product safety, quality or efficacy and will initiate corrective actions as necessary. To the extent Supplier investigates any complaints relating to the safety, efficacy or quality of a product, Supplier will notify Aspen within fifteen (15) days of Supplier's findings. Supplier will maintain a complaint file and records relating to each complaint as required by Legal Requirements.

**11. Adverse Event Reports.** If Supplier is the legal manufacturer for a finished product, Supplier is responsible for making all filings and reports relating to an Adverse Event relating to a product with regulatory authorities. Aspen will report to Supplier any information of which Aspen becomes aware that may constitute a product-related adverse event, including any event involving death, serious injury or potential malfunction of a product, whether or not such event has been definitively determined to be associated with a product (each an "Adverse Event"). Unless otherwise agreed in writing, any other reporting

obligations relating to the product will be the responsibility of Supplier.

**12. Recalls.** Supplier will notify Aspen no later than twenty-four (24) hours of discovery if any product is alleged or proven to be the subject of a Recall or if Supplier believes a Recall may be necessary with respect to a product. The parties will cooperate in the handling and disposition of such Recall; provided, however, Aspen's quality assurance department may institute a Recall due to any defect it considers sufficiently serious. Supplier will provide at no charge (a) technical assistance and information as Aspen may request in order to enable Aspen to investigate quality issues that may be related to or caused by the products; and (b) reasonable cooperation and assistance to Aspen in executing a Recall. Supplier will be responsible for all expenses incurred by Aspen and its customers in undertaking a Recall to the extent such Recall results from Supplier's failure to manufacture the products in accordance with the products' specifications or this Agreement or from Supplier's negligence, bad faith or willful misconduct. For purposes of this Agreement, the expenses of the Recall include the reasonable direct expenses of notification and return or destruction of recalled products, the cost to replace or refund the price of the recalled product and any costs directly associated with distribution of replacement product. In all cases, the parties will conduct any Recall in a manner that is appropriate and reasonable under the circumstances and in conformity with accepted trade practices and Legal Requirements.

**13. Audits.** "Audit" will mean an audit of Supplier's facility for purposes of reviewing Supplier's procedures, processes, facilities, personnel and records used in or created during the design, manufacture or distribution of the product to assure conformance to this Agreement and applicable Legal Requirements. Aspen will have the right to conduct Audits as needed to evaluate the Supplier. Aspen will comply with all of Supplier's facility rules regarding safety and security notified by Supplier to Aspen. Each Audit will be conducted during Supplier's business hours and, unless a shorter period is required by Aspen because of an urgent issue, upon at least fourteen (14) days' prior written notice to Supplier. During an Audit, upon Aspen's request, Supplier will make available for Aspen's review, interview and inspection all equipment, personnel and facilities used in or in relation to the manufacture of the product, records, complaints and supporting documents (e.g., manufacturing, analytical and testing documentation) with respect to the product and materials used in the manufacture of the product. Aspen will have the right to obtain copies of records concerning the product. After the Audit, Aspen will provide a written audit report. Within thirty (30) days of audit report receipt, Supplier will provide a written response to all findings that details corrective action to be implemented. Supplier will ensure that all corrective actions are implemented. Aspen may confirm corrective action by performing a follow-up Audit.

**14. Third-Party Audits.** Supplier agrees to cooperate with third-party audits by Aspen's certifying body as required to maintain Aspen's ISO 13485 and/or MDSAP certifications.