



PROCUREMENT TERMS AND CONDITIONS

ALL GOODS AND SERVICES PROCURED BY GSS FROM SUPPLIER, AS DEFINED IN THE PARTIES' DISTRIBUTION AGREEMENT, SHALL BE IN ACCORDANCE WITH THE FOLLOWING TERMS AND CONDITIONS

1. ACCEPTANCE. These Procurement Terms and Conditions and the Distribution Agreement to which they are attached (the "Distribution Agreement") (the Distribution Agreement and these Terms and Conditions collectively are referred to as this "Agreement") do not constitute an acceptance by GSS of any prior proposal, quote or offer to sell. Any reference to such is solely for the purpose of incorporating the description and/or specifications of the goods and services contained therein, but only to the extent that such description or specification does not conflict with the description and specifications set forth in the Agreement.

2. COMPLETE AGREEMENT. This Agreement constitutes the complete agreement between the parties and may not be altered or modified except in writing duly executed by each party. Any additional terms or conditions contained in Supplier's order acknowledgment, or in any other Supplier document, shall be deemed objected to by GSS without the need for further notice of objection, and shall be of no effect, nor shall they be binding upon GSS under any circumstances unless expressly accepted by GSS in writing. GSS's acceptance or rejection of one or more additional terms or conditions shall not constitute an acceptance of any other additional term or condition. Trade custom, trade usage, course of dealing, and past performance is superseded by this Agreement and shall not be used to interpret this Agreement.

3. CHANGES. GSS at any time shall have the right to make changes to its order, including without limitation, in the quantities, specifications, drawings, instructions, or delivery schedule. Any such change that has a significant impact on Supplier's time or cost of performance shall entitle either Supplier or GSS to an equitable adjustment. However, no additional charge will be allowed unless asserted by the Supplier within ten (10) business days after the change is ordered and authorized by GSS in writing. Information, such as technical direction or guidance provided to Supplier by GSS's representatives in connection with Supplier's performance hereunder, shall not be construed either as a change within the meaning of this provision or as direction to proceed outside the scope of this Agreement.

4. CANCELLATION. GSS may cancel its order in whole or in part upon two (2) business days' notice to Supplier, without liability to GSS. Cancellation will not have the effect of waiving damages to which GSS might otherwise be entitled. Product shipped after cancellation notification will be returned to the Supplier at the Supplier's expense.

5. NO PUBLICITY. Neither supplier or GSS shall issue or cause to be issued any press release, public announcement or disclosure of any kind or nature whatsoever or otherwise disclose the existence of the transactions contemplated hereby except as and to the extent that both parties jointly agree to such press release, public announcement or disclosure previously and in writing.

6. DELIVERY. TIME IS OF THE ESSENCE for delivery to GSS hereunder. Supplier shall promptly provide written notification to GSS of any possible or actual delay or cancellation in performance hereunder and shall provide all relevant information concerning the cause for such delay. In no event, however, shall such notice relieve Supplier of its obligations under this Agreement. If delivery is not made within the time specified, GSS may cancel the entire order or any undelivered portion thereof. Payments due to Supplier may be offset against sums owed to GSS by Supplier. Deliveries shall be strictly in accordance with the schedule set out or referred to in this Agreement and in the exact quantities ordered. In no event shall GSS be liable for any excess goods shipped by Supplier. GSS reserves the right at Supplier's expense to return goods shipped not in accordance with the terms of GSS's order and this Agreement.

7. WARRANTY. Supplier warrants and guarantees that its goods and services (collectively "Products"):

- (a) will comply with all its published specifications and requirements;
- (b) will be of merchantable quality, free from any latent or patent defects;
- (c) will be safe and fit for the Supplier's intended application;
- (d) shall reference true weights, measures, sizes, legends or descriptions indicated;
- (e) will be of comparable quality as all samples delivered to GSS, if any; and
- (f) shall comply with all applicable laws, rules, regulations, licenses, permits, ordinances, codes and or standards. This warranty and guaranty shall be in addition to any statutory or implied warranties, and warranties of broader scope and service warranties and guarantees given to GSS by the Supplier, and shall survive inspection, test, acceptance, and payment, and shall run to GSS, its successors, assigns, and Customers.

8. NONCONFORMANCE. Products or services that do not conform to the requirements of this Agreement may be rejected, at GSS's sole option. All costs with respect to the repair, replacement or refund of the nonconforming Products, including packing, packaging and freight charges, shall be at the Supplier's expense. Without limiting the foregoing, Supplier shall promptly respond to all Product Nonconformances submitted by GSS and shall take all necessary and appropriate corrective action.



9. PROPRIETARY RIGHTS. Supplier hereby acknowledges that GSS is the owner of the trademarks and trade names connoting GSS or GSS products which it may elect to use in the distribution and sale of the Products, and that Supplier has no right or interest in such trademarks and trade names. Supplier agrees that it will not use GSS's name, trade name or trademark in any way without the prior express written consent of GSS. Supplier hereby grants to GSS the royalty-free license to use Supplier's trademarks on the Products, it being expressly understood that if GSS elects to use Supplier's trademarks during the term of the Agreement, GSS shall properly do so and shall discontinue the use of such trademarks in any new material published after the termination hereof. Following the termination of this Agreement, Supplier grants to GSS the right to continue to use Supplier's trademarks as necessary in connection with the sale or service of Products purchased by GSS during the term of this Agreement.

10. Intellectual Property. Supplier represents and warrants that it maintains all rights of ownership or use in any trademark, patent, copyright or any other Intellectual Property necessary to sell the Products to GSS pursuant to this Agreement ("Intellectual Property"). Supplier agrees to defend, indemnify and hold GSS (and its agents, representatives, employees, officers, directors, affiliates, successors, assigns, and Customers) harmless from any and all claims, demands, actions, damages and liabilities (including legal fees) involving the infringement of any third-party patent, trademark, copyright or other intellectual property right, or the misappropriation of any trade secret, by reason of the manufacture, use, or sale of said Products by GSS. Without limiting the foregoing, if any of the Products becomes the subject of any claim, suit or proceeding for infringement of any patent, Supplier will in consultation with GSS and at Supplier's sole expense, (i) obtain for GSS the right to use, lease or sell the Product, (ii) replace the Product, (iii) modify the Product, or (iv) remove the Product and refund the full purchase price paid by GSS.

11. WORK ON OTHER PARTY'S PREMISES. Where Visiting party either is required to enter premises occupied by the other party's or under the other party's control, including Customer sites, to perform services or otherwise, Visiting party will inspect the premises involved, will provide all necessary safeguards for persons it brings on to the premises, will defend, protect, indemnify and hold occupying party and its successors, assigns and employees harmless from and against all claims, losses, expenses, damages and liabilities, direct, incidental or consequential arising from damage to or loss of property by visiting party Visiting party, its employees or others, or from personal injuries to or death of Visiting party, Visiting party's employees or others resulting from or incidental to the presence of such persons on the premises involved WHETHER THE SAME RESULTS IN WHOLE OR IN PART FROM OCCUPYING PARTY NEGLIGENCE OR OTHER FAULT BY ACT OR OMISSION, OR THAT OF OCCUPYING PARTY'S EMPLOYEES OR OTHERWISE, IT BEING THE INTENT OF THIS PROVISION TO ABSOLVE AND PROTECT OCCUPYING PARTY AND ITS SUCCESSORS, ASSIGNS AND EMPLOYEES FROM ANY AND ALL LOSS BY REASON OF VISITING PARTY'S PERFORMANCE OF WORK ON occupying party's PREMISES, and will maintain workmen's compensation insurance covering all employees performing services related to this Agreement on premises occupied by occupying party or under occupying party's control. Visiting party expressly agrees to waive any provisions of the applicable workers compensation law, whereby Visiting party could preclude its joinder as an additional defendant or avoid liability for damages, contribution or indemnity.

12. RIGHT-OF-ACCESS. GSS reserves the right, upon reasonable notice and during normal business hours, to verify purchased Products at Supplier's premises and to inspect Supplier's work hereunder to ensure that all relevant standards and specifications are met. Any such inspection by GSS does not absolve Supplier of the responsibility for the quality of Products, nor shall it preclude subsequent rejection by GSS.

13. PACKING & SHIPPING. No charge shall be allowed for handling, packing, crating, drayage or storage without written permission of GSS. Goods shall be packaged in a method to preserve and protect from damage and/or degradation and shall be suitably prepared for shipment by Supplier in accordance with acceptable commercial practices and in compliance with all applicable laws. Supplier shall cause the goods to be labeled and marked to conform to all requirements of all applicable federal, state and local laws. Supplier shall identify GSS's purchase order number on Supplier's invoice, packing list, bill of lading or on outer packages. Supplier shall attach a packing list to all shipments, in addition to forwarding a copy of such invoice to GSS. For orders greater than \$50,000 that are drop shipped to the customer a shipment tracking number must be provided to receive payment. Unless otherwise provided in this Agreement, all sales within the USA are FCA Destination, and all international sales are DDP (GSS's designated location) Incoterms 2020. Where required by law, Supplier must satisfy U.N. performance tested packaging. Additionally, regardless of whether U.N. performance tested packaging is required by law, all packaging must satisfy International Safe Transportation Association (ISTA) 3A standards.

14. Trade Compliance. Supplier shall provide GSS with the following, as applicable: a) Harmonized Tariff Commodity Code; b) Export Control Classification Number (ECCN); c) International Traffic in Arms (ITAR) category; d) NRC controls.

15. PRICING. GSS's orders must not be filled at prices higher than last quoted by Supplier or as set forth in this Agreement unless GSS consents in writing. Supplier represents that the prices to be paid or otherwise charged to GSS are not any higher than the lowest price for such goods or services offered by Supplier to any other of its Customers of similar sales quantity or revenue. Supplier shall be responsible for and pay all federal, state, and local sales, use, income, excise, property, employment, and other taxes similar to, or differing from, any of the foregoing, incurred or levied on or in connection with the manufacture of goods, provision of services, or relating to Supplier's own property. GSS shall be responsible only for taxes arising from its ownership of the Products. Supplier agrees to indemnify GSS against any loss, liability or expense (including reasonable attorney's fees) resulting from Supplier's failure to pay such taxes, fees, duties, assessments, charges or conditions.

16. PAYMENT. Payment by GSS hereunder shall not be deemed an acceptance of the goods or services performed hereunder by Supplier.

17. TITLE. Supplier warrants full, unrestricted title to all goods and services furnished hereunder, free and clear of all liens, security interests and encumbrances. Care, custody and control of, and title to all Products remain with Supplier until such time as GSS takes ownership dictated by the agreed upon Incoterms. Supplier shall carry on its work and manufacture of Products at its own risk until the Products are completed and accepted by the GSS. In the case of accident, destruction or injury to the Products before the final completion and acceptance, Supplier shall repair or replace such Products at its own expense and to GSS' satisfaction.

18. HAZARDOUS MATERIALS. Supplier will notify GSS in writing no later than upon execution of this Agreement if Products furnished are subject to laws or regulations relating to hazardous or toxic substances, whether for shipment or use, or when disposed of, to regulations governing hazardous wastes, or any other applicable environmental, health, or safety laws or regulations. Instructions for shipping, handling, warnings, and



material safety data sheets shall be provided with each shipment. Supplier shall submit to GSS with each shipment, a copy of all relevant (M)SDS sheets. Supplier agrees to and shall accept, at its facility, all of GSS's unsold or expired Products containing hazardous chemicals, materials or substances for disposal, recycling or use. GSS shall be responsible for packing and transportation costs to Supplier. Supplier shall be responsible for all other costs, including, without limitation, any costs associated with Supplier's disposal, recycling or use.

17. INDEMNITY & INSURANCE. Supplier agrees to defend, indemnify and hold GSS (and its agents, representatives, employees, officers, directors, affiliates, successors and assigns, Customers, and all subsequent users of the Products) harmless from all claims, demands, actions, damages, and liabilities (including reasonable attorney's fees) in any way connected with the goods or services provided to GSS hereunder, the breach of any of the terms and conditions contained herein, or any act or omission of Supplier, its agents, employees, or subcontractors. Supplier agrees to procure and maintain on an occurrence form basis product liability insurance with respect to the Products and contractual liability coverage relating to this Agreement, if any, with insurer(s) having Best's rating(s) of A- or better, naming GSS as an additional insured (Broad Form Vendors Endorsement), with minimum limits in each case of \$2,000,000. Supplier shall promptly furnish to GSS a certificate of insurance and renewal certificates of insurance evidencing the foregoing coverages and limits. The insurance shall not be canceled, reduced or otherwise changed without providing GSS with at least thirty (30) days prior written notice.

18. RECALLS. Should a recall be necessitated due to a defect or non-conformance of the Products, Supplier shall bear all costs and expenses of such recall, including without limitation, costs of notifying Customers, returning Products, Customer refunds, lost profits, and any expenses incurred to meet obligations to third parties.

19. COMPLIANCE WITH LAWS. Supplier shall comply with all applicable international, federal, state, county, and municipal statutes, laws, regulations, codes, standards, ordinances and orders in its performance hereunder and shall be responsible for all fees associated with such compliance, licenses, permits, certifications, bonds, taxes, duties, tariffs and other applicable fees. Without limiting the foregoing, Supplier will comply with all customs laws and requirements of the U.S. (including specifically the U.S. Export Administration Act) and of each country in which the Products are made or likely to transit with respect to (a) the labeling of the Products and their packaging, (b) the export and import of the Products and the subsequent distribution of the Products to GSS and/or directly to the GSS's Customers, including the completion and submission of all required documentation, and the payment of all taxes, duties, tariffs and similar expenses. In addition, Supplier hereby acknowledges, represents and warrants (i) that Supplier WILL NOT provide any Products that in whole or in part have been transferred, exported or imported, directly or indirectly, from a country or nation thereof, subject to restrictions under applicable laws and regulations, including but not limited to inclusion on the Export Administration Regulations' Denied Party List or any similar list published by a United States or foreign agency; (ii) Supplier is not located in, under the control of, or a national resident of any such restricted country; (iii) the Products have not been produced, in whole or in part, by prison labor, sweatshop labor, abusive forms of child labor, slave labor, or by other labor practices in violation of applicable law; and (iv) unless otherwise agreed to in writing by GSS and Supplier, Supplier shall serve as the Importer of Record for the Products and shall comply with all applicable laws, be responsible for all applicable fees, and assume all obligations incurred as the Importer of Record.

20. ASSIGNMENT. Neither party shall assign this Agreement or any rights or work performed hereunder without the prior written consent of the other party; provided however, that either party may assign, without the other's consent, this Agreement to any person or other legal entity (other than a competitor of the other party or a person or an entity that controls, is controlled by, or is under common control with such competitor) into which such Party has merged or that has otherwise succeeded to all or substantially all of the business or assets of such party to which this Agreement pertains by merger, consolidation, reorganization, or otherwise. Any attempted assignment without such consent shall be null and void and shall be grounds for termination of this Agreement by GSS.

21. WAIVER. No failure to exercise, and no delay in exercising, on the part of GSS any right, power or privilege hereunder will operate as a waiver, nor will any single or partial exercise of any right, power or privilege preclude further exercise of the same right, power or privilege.

22. VALIDITY OF PROVISIONS. In the event that any provision or any part or portion of any provision of this Agreement shall be held to be invalid, void or otherwise unenforceable, such holding shall not affect the remaining parts or provisions hereof.

23. GOVERNING LAW & VENUE. This Agreement shall be governed in accordance with the laws of the Commonwealth of Virginia, without reference to any conflict of law provisions. Unless the parties agree otherwise in writing, in the case of any unresolved dispute relative to this Agreement, said dispute shall be submitted to a board of arbitrators. The board shall consist of one arbitrator selected by Supplier, one arbitrator selected by GSS, and a third arbitrator selected by the two arbitrators selected by the parties. A decision by a majority of the board of arbitrators shall be binding on both parties. The parties agree the UN Convention on Contracts for the International Sale of Goods shall not apply to the sale of goods hereunder.

24. CONFIDENTIALITY. Each party ("Recipient") expressly agrees to hold as confidential certain information which is provided by the other party ("Discloser") (such information "Confidential Information"). Supplier expressly acknowledges and agrees that GSS's Customer names, addresses, key contacts, Customer purchase history, documents and information in any way related to the marketing, sale or distribution of any products are and shall be the Confidential Information of GSS, regardless of whether such information is expressly marked as "confidential" by GSS. Additionally, the terms of this Agreement shall constitute Confidential Information. Supplier agrees that it will limit the Confidential Information that it provides to GSS to information concerning sources, new products development and financial information unless GSS consents to the disclosure of additional information. In the event Confidential Information is exchanged according to these guidelines, such information will be retained by the Recipient in confidence during the term of this Agreement and for a period of five (5) years following the termination of this Agreement. The transmittal of such information is and shall be upon the express condition that the information is to be used solely to effectuate this Agreement; and the Recipient shall not use, publish, or disclose said information, in whole or in part, for any purpose other than that stated herein. Notwithstanding the foregoing, the above restrictions on disclosure and use shall not apply to any information which the Recipient can show by written evidence, was known to it at the time of receipt, or which may be obtained from third parties who are not, to the Recipient's



knowledge, bound by a confidentiality agreement to the Discloser, or which is in the public domain, or which may be independently developed without use of the Confidential Information.

25. GRATUITIES. Neither the Supplier, nor anyone in privity with the Supplier, shall have accepted or accept, or give or agree to give, any gratuity from any person, including but not limited to GSS, in connection with the purchase of Products.

26. AUDIT RIGHTS. During the term of this Agreement or for a 2 year period after placement of this Agreement or termination of this Agreement, GSS shall have the right upon reasonable notice and during normal business hours to audit the facilities and records of Supplier as reasonably necessary and as subject to confidentiality agreements in order to ensure compliance with the terms of this Agreement; provided that GSS will use commercially reasonable efforts to minimize any inconvenience to Supplier as a result of such audit.

27. FORCE MAJEURE. Neither Supplier nor Distributor shall be liable for its failure to perform hereunder, as a result of any contingency beyond its reasonable control, including acts of God, fires, epidemics, pandemics, floods, earthquakes, wars, sabotage, accidents, acts of terrorism, lockouts, strikes, labor disputes or shortages, any government laws, ordinances, rules, regulations, action or inaction, whether valid or invalid (including but not limited to priorities, requisitions, allocations and price adjustment restrictions), inability to obtain supplies, raw materials, products, equipment or transportation, and any other similar contingency. Each party shall notify the other party of the existence of any such condition within twenty (20) days of the first day that such condition becomes known

28. CONFLICT MINERALS. Supplier is expected to ensure that parts and products supplied that contain “conflict minerals” (i.e., columbite-tantalite (coltan), cassiterite (tin), gold, wolframite (tungsten), or their derivatives) are “DRC conflict-free” (i.e., that such “conflict minerals” do not directly or indirectly finance or benefit armed groups in the Democratic Republic of the Congo or an adjoining country). Supplier will or has established appropriate policies, due diligence frameworks, and management systems that are designed to accomplish this goal. Supplier will provide such information to GSS and to take such other actions as GSS requests to enable GSS to comply with its obligations under regulations of the Securities and Exchange Commission promulgated under Section 13(p) of the Securities Exchange Act of 1934, as amended.

29. GOVERNMENT PROCUREMENT PROVISIONS:

Supplier shall abide by the requirements of 41 CFR §§ 60-1.4(a), 60-300.5(a) and 60-741.5(a), as applicable. These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities and prohibit discrimination against all individuals based on their race, color, religion, sex, or national origin. Moreover, these regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, national origin, protected veteran status or disability.

Supplier represents that the Products are marked with regards to origin in accordance with GSS’s specifications, U.S. requirements pursuant to 19 CFR 134 and all other applicable statutes, laws, regulations, codes, standards, ordinances and orders. Upon GSS’s request, Supplier will promptly provide certification to evidence the country of origin of such Products and/or materials purchased hereunder. Supplier shall protect, indemnify, exonerate and hold GSS harmless from and against any and all suits, claims, liability, losses, liens and demands (including reasonable attorneys’ fees), fines, costs, criminal and civil penalties, causes of action or any other obligations arising out of or in any matter connected with Supplier’s failure to comply with any applicable laws, regulations and/or other requirements.

To the extent the Products are commercial items as defined by Federal Acquisition Regulation (FAR) 2.101 (“Commercial Items”), FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders - Commercial Items – clauses in paragraph (e)(1) only, are incorporated into this Agreement by this reference. The Parties acknowledge that pursuant to Title 48 of the FAR, GSS is required to flow down specific contract clauses to its subcontractors. Supplier accepts the mandatory supplier flow downs in FAR 52.212-5(e). In addition, GSS may also otherwise request in writing to Supplier on a case-by-case basis that additional or different terms than those contained herein be incorporated into a specific GSS purchase order by an agreement signed by authorized representatives of both Supplier and GSS.

Supplier shall abide by FAR 52.204 -23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JULY 2018)

Supplier shall abide by FAR 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment developed or Provided by Huawei Technologies Company or ZTE Corporation or any subsidiary or affiliate of such entities (AUG 2019)

To the extent the Products are Commercial Items for electronic parts or assemblies containing electronic parts, Supplier shall comply with Defense Federal Acquisition Regulation Supplement (DFARS) 252.246-7007 - Contractor Counterfeit Electronic Part Detection and Avoidance System

30. Dangerous Goods. If products consist of, contain, or are packaged with lithium batteries, supplier agrees that batteries meet the provisions of the UN Model Regulations on the Transport of Dangerous Goods Chapter 2.94 and meets the requirements of each test of the Manual of Tests and Criteria Part III sub-section 38.3. In addition, supplier agrees to provide the lithium battery test summary required by the above referenced UN documents upon request. Supplier agrees that UN3480, Lithium-Ion Batteries (stand-alone lithium-ion batteries) will not be shipped to GSS at a state of charge (SOC) greater than 30% of their rated design capacity in accordance with IATA Packing Instruction 965. UN specification packaging’s intended to be used for containment of dangerous goods by the end user including but not limited to empty drums, boxes, and spill kits, must include closure instructions with shipment of the product in accordance with 49 CFR 178.2. The closure instructions may be printed on the actual packaging or as a paper copy accompanying the product.

If the end user of the Products or Services will in any way relate to the federal healthcare programs, the following provision will apply:



31. HEALTHCARE REPRESENTATIONS. The Office of Inspector General (“OIG”) Special Advisory Bulletin on the Effect of Exclusions on Participation in Federal Health Care Programs clarifies the OIG’s sanction authority to impose civil money penalties and deny reimbursement under federal health care programs of any and all products or services if products or services are provided by an excluded entity. (Federal Register, September 30, 1999, Vol. 64, No. 189, pp. 52791-52794.) The OIG Special Advisory Bulletin specifically provides that “items or equipment sold by an excluded manufacturer or distributor, used in the treatment of beneficiaries and reimbursed, directly or indirectly, by a federal health care program violate the OIG’s exclusion.” Supplier represents and warrants that neither it, any of its subsidiaries or affiliated businesses, nor any officers, directors, or other key personnel of same, have been (a) convicted or threatened with conviction of any health care related offense, whether state or federal, or (b) been or threatened with being debarred, excluded, or otherwise listed or rendered ineligible for participation in any federal or state healthcare program, as that term is defined by 42 USC §1320a-7b(f) by any state or federal agency (collectively referred to herein as being “Excluded”). If Supplier, any of its subsidiaries or affiliated businesses, or any officers, directors, or other key personnel of same, are Excluded or otherwise receive from authorities a notice of intent to Exclude from federal or state healthcare program participation, Supplier shall immediately notify GSS of the same in writing within forty-eight (48) hours. Upon notice of same, GSS shall have the right to immediately terminate the order and/or this Agreement in its sole discretion without cost or penalty. In the event Supplier breaches or otherwise fails to comply with any provision of this Paragraph, Supplier hereby agrees to defend, indemnify and hold GSS harmless from and against any loss, claim, suit, expense or obligation arising out of or resulting from any such breach or noncompliance, including, but not limited to, sanctions, penalties, or fines incurred under the federal Civil Monetary Penalty Law (Section 1128A of the Social Security Act), the Health Insurance Portability and Accountability Act of 1996 or the Balanced Budget Act of 1997.

If the Products to be provided are regulated by the United States Food & Drug Administration (FDA), the following provisions will apply:

32. FDA COMPLIANCE REQUIREMENTS. Supplier agrees that it will comply with all aspects of the FDA Regulations as detailed in Title 21 C.F.R. (Food & Drugs) § 1-1499. If Supplier is not the manufacturer of the Products, Supplier shall ensure that the manufacturer is compliance with the requirements stated herein. Without limiting the foregoing, Supplier specifically agrees to the following (or agrees to require compliance of the manufacturer of the Products regarding the following):

(a) Supplier shall ensure proper registration of all establishments and products involved in the development, manufacture and distribution cycles of the Products and shall comply in all respects with any laws relating thereto.

(b) Supplier shall register and remain registered with FDA as the Specification Developer and the Manufacturer of the Products. If Supplier is not the manufacturer of the Products, Supplier will ensure that the manufacturer registers and remains registered with the FDA as the Specification Developer and the Manufacturer of the Products.

(c) Supplier shall ensure that all Medical Devices produced in their establishment(s) are listed with the FDA and conform to the regulations pursuant to FDA Federal Code of Regulations (C.F.R.) Title 21, Subchapter H, Part 807.

(d) Supplier shall register with FDA all Foreign Establishments manufacturing FDA-regulated Products according to the applicable laws and regulations and hereby agrees to perform routine audits of such Foreign Establishments during the term of this Agreement.

(e) All Product quality issues, Medical Device Reporting, reports of corrections and removals and Medical Device Tracking must be performed in a timely manner by Supplier and as required by federal laws and regulations with appropriate notice provided to GSS.

(f) Supplier must assure that any Products requiring sterilization comply with all applicable law and Good Manufacturing Practices, as defined by FDA regulations.

(g) Supplier will maintain all required documentation as mandated by FDA regulations and as required pursuant to Supplier’s Quality System. Additionally, Supplier will comply with and will maintain a process to document such compliance in accordance with the Quality System Regulations (21 C.F.R. § 820). Supplier will make any and all such documentation available for review by GSS (or its designee) pursuant to the terms of this Agreement.

(h) Supplier will cooperate with GSS to allow GSS (or its designee) to audit Supplier or any of Supplier’s manufacturers in the supply chain as needed and upon request.

(i) With respect to any labels and packaging (including specifically any Instructions for Use and packaging inserts), all such labels and packaging must (i) be approved by GSS in advance, and (ii) if required by law, any such labels and packaging must be approved in advance by the FDA.

(j) With respect to process changes, Supplier will communicate in a timely manner any raw material, formulation or process change to GSS.

(k) If required by law, Supplier must coordinate any Customer notifications in conjunction with GSS’s Quality and Regulatory Departments. Examples of such required communication would be: (i) quality issues, (ii) process changes, (iii) recalls, (iv) Medical Device Reporting, (v) reports of corrections and removals, and (vi) Medical Device Trading.

(l) Supplier, as the Specification Developer and Manufacturer, will be responsible for notifications, as required, to FDA pursuant to 21 C.F.R. § 1-1499. If Supplier is not the manufacturer of the Products, Supplier will cause the Specification Developer and Manufacturer to provide such notices.



(m) Notwithstanding the foregoing, in the event that the Products are manufactured or transported by Supplier in such a way that another country's equivalent of the U.S. FDA may have jurisdiction (e.g. the People's Republic of China), Supplier agrees that it will also comply with any such laws and regulations which relate in any way to the marketing, manufacture, distribution or transportation of the Products.

33. FDA PRODUCT INFORMATION. Supplier agrees that it will provide the following information to GSS with respect to each FDA regulated Product:

- 1) FDA medical device listing number (MDL)
- 2) FDA Product Code (3 digit alpha code)
- 3) FDA device description
- 4) 510k number (if applicable)
- 5) Establishment number

If Supplier is not the manufacturer of the Products, Supplier will ensure that the manufacturer is in compliance with the above and will obtain the foregoing and provide such information to GSS.