
1.0 SUBJECT:

Seller and Gaskin Manufacturing Corporation agree and acknowledge the following responsibilities related to the distribution of the Products distributed by Gaskin Manufacturing Corporation are consistent with the current versions of FDA regulations promulgated under 21 CFR Part 820 for medical devices (“FDA regulations”), ISO 13485 International Regulatory Standard for Medical Devices and/or AS9100 Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations.

Seller produces or supplies products and/or services for Gaskin Manufacturing Corporation as per contract or purchase order.

Seller, in the production of the aforesaid products, agrees to produce or supply products and/or services within the Seller’s existing state of the art and Quality Management System at the time of Gaskin Manufacturing Corporation’s audit and/or approval of the Seller. The Quality and Quality Management System requirements for the Seller will be specified during the audit and/or qualification process by Gaskin Manufacturing Corporation.

If Gaskin Manufacturing Corporation requests that special regulations and guidelines which are not (yet) generally known and recognized are to be considered for certain products, Gaskin Manufacturing Corporation shall inform Seller thereof in writing.

In the case of conflict between this Supplier Quality Agreement and any other agreement or contract between Gaskin Manufacturing Corporation and Seller, the Quality Requirements and Specifications set forth within this Supplier Quality Agreement shall supersede any described or documented within any other contract or agreement.

2.0 QUALITY MANAGEMENT SYSTEM: Seller will maintain a Quality Assurance program to ensure compliance with Gaskin Manufacturing Corporation’s purchase requirements. The Seller’s Quality Assurance program shall be subject to approval by Gaskin Manufacturing Corporation.

3.0 RIGHT OF ACCESS: The Seller shall provide the “Right of Access” to all applicable areas of their facilities and applicable records at any level of the supply chain involved in the Buyer’s orders. This “Right of Access” includes Gaskin Manufacturing Corporation, our customers and FAA, EASA or other regulatory agencies.

4.0 RECORD RETENTION: Records created by the Seller and retained by the Seller regarding products provided and traceability shall be maintained for a minimum of 7 years unless otherwise notified and shall be available upon request within 24 hours. The Seller is expected to maintain lot control with traceability to the purchase order. A lot consists of pieces of a single part number and composition; manufactured under essentially the same conditions, and at essentially the same time.

5.0 SPECIFICATIONS: If a Gaskin Manufacturing Corporation document specifies a specification with a revision stated, then that specification and revision is required, regardless of the status of the specification as canceled, superseded, replaced or obsolete. Otherwise, the current released version of the specification is required.

6.0 GASKIN MANUFACTURING CORPORATION SPECIFIED PROVIDERS: Should Gaskin Manufacturing Corporation require a specific provider for any of the products provided by the Seller, these will be noted on the Purchase Order. The Seller is required to use the provider identified. This requirement also applies to special process providers.

7.0 REQUIREMENTS FOR PERSONNEL: Seller to ensure personnel are certified or qualified when the processes being used to produce the product require it. Examples include non-destructive testing, welding, soldering and other processes that have a high degree of human intervention and control. Seller to ensure all employees involved in the manufacture of product for Gaskin Manufacturing Corporation are aware of their contribution to product conformity, their contribution to safety, and the importance of ethical behavior.

8.0 DESIGN CONTROL: Gaskin Manufacturing Corporation or their clients retain sole ownership of design and design control.

9.0 REQUIREMENTS FOR TEST SPECIMENS: Seller to meet requirements defined within the purchase order for test specimen manufacture, quantities, retention, and inspection/verification for acceptance. Test specimens must be properly preserved throughout the retention period. Test specimen records to be maintained for 7 years, unless otherwise specified.

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- 10.0 SAMPLING PLANS AND KEY CHARACTERISTICS:** Seller to ensure test and inspection plans are implemented to ensure product complies with specified requirements and end user's needs. Sampling plans must conform to ANSI/ASQ Z1.4. Seller to comply with requirements applicable to critical items, such as Key Characteristics (reference AS9103), when specified.
- 11.0 REQUIREMENTS FOR FLOW DOWN TO SUB-TIERS:** Seller must flow down applicable requirements, including statutory or regulatory requirements, such as DFARS and DPAS, which may affect the item(s) ordered by Gaskin Manufacturing Corporation, to its sub-tier source(s) and ensures the sub-tier source(s) conforms to these requirements.
- 12.0 CHANGE NOTIFICATION:** Seller to notify Gaskin Manufacturing Corporation of changes in product and/or process definition; and obtain our prior approval. Changes include relocating production, inspection or processing facilities; transferring work between facilities; and initiating any changes in the source of items procured by the Seller that may have a significant effect on products or processing of products for Gaskin Manufacturing Corporation. Any change which may significantly affect product quality, reliability or integrity must be communicated to Gaskin Manufacturing Corporation for approval. A change in ownership or a change in the individual designated as the management representative with respect to the Sellers Quality/Inspection System shall be construed as a facility change and requires the Seller to notify Gaskin Manufacturing Corporation
- 13.0 NONCONFORMING PRODUCT:** Seller disposition is NOT authorized. Seller must notify Gaskin Manufacturing Corporation of nonconforming product. The Seller may not perform any repairs on products damaged or found to be discrepant unless such repairs are specifically permitted by the applicable drawing or specification or are specifically authorized by Gaskin Manufacturing Corporation in writing for each occurrence. Unless specifically authorized by Gaskin Manufacturing Corporation, this prohibition also applies to reworking products by removing plating (stripping) and re-plating. Sellers shall not ship nonconforming material without first obtaining written approval from Gaskin Manufacturing Corporation. Where repair has been accomplished, the Seller shall include with the shipping documents a list of the products that have been subjected to such Gaskin Manufacturing Corporation approved repair and the method used. Gaskin Manufacturing Corporation is required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. Gaskin Manufacturing Corporation must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. These notifications must adhere to the requirements of FDA 21CFR Part 803.
- 14.0 COUNTERFEIT PARTS PREVENTION:** Seller represents and warrants that only new and authentic materials are used in products to be delivered to Gaskin Manufacturing Corporation under this order and that the products delivered contain no counterfeit parts or suspect counterfeit parts.
- 15.0 PERFORMANCE:** Gaskin Manufacturing Corporation has established a program in which Seller performance will be evaluated periodically. The performance will be based on the quality and on-time delivery of every lot received. The Seller is to have a minimum quality performance rating of 80%. The overall performance rating is based on nonconformance, CAPA, deviation and on-time delivery; the delivery rating is based on each lot with a plus/minus (+/-) 1-day window.
- 16.0 INTERACTIONS WITH GASKIN MANUFACTURING CORPORATION:** To ensure timely and consistent communication, Gaskin Manufacturing Corporation requires the Seller to contact appropriate personnel for certain specific reasons. Points of contact are:

Order Confirmation: Buyer
General Order Inquiries: Buyer
Scheduling: Buyer
Engineering Support: Manufacturing Engineer
Quality Support: Quality Manager

This Supplier Quality Agreement shall apply for all deliveries from Seller to Gaskin Manufacturing Corporation. It shall be valid for the duration of delivery relationships between the parties and shall not be terminable independently.

Document Name: Supplier Quality Agreement

Rev: 1

Date: _____

Date: _____

Seller's Authorized Representative (Signature)

Gaskin Manufacturing Corp. Authorized Representative (Signature)

Seller's Authorized Representative (Print)

Gaskin Manufacturing Corp. Authorized Representative (Print)

Seller's Authorized Representative (Title)

President / Owner

Gaskin Manufacturing Corp. Authorized Representative (Title)