1.0 PURPOSE

This document establishes the requirements that must be followed by GCM suppliers of production items and services.

2.0 SCOPE

This procedure applies to all procured materials and services that are incorporated into product shipped to the customer.

3.0 LEGAL COMPLIANCE

Comply with the laws and regulations of the applicable legal systems.

4.0 REQUIREMENTS

1. **Product Requirements**
   Products and services must be provided to the stated requirements as specified by the purchase order (PO) and accompanying information such as part number, part revision, and part drawing. Other requirements such as directed sources, critical features, GCM approvals, special testing or inspection, and certifications will be listed on the part drawing or as a note on the purchase order, where the part drawing takes precedence. It is the supplier's responsibility to obtain any industry standard requirements referenced on the drawing or PO.
2. **Product Inspection and Verification**
   Inspection of product must be completed by the supplier in a manner consistent to provide a basis that is mathematically valid, and the sampling plans do not allow for the pass through of defective parts. GCM may require production process verification, such as paint chip samples, process flow diagram, machine parameters, etc. GCM may require test specimens for approval, inspection/verification, root cause analysis, etc. GCM will advise the supplier of any such requirements.
3. **Change Control**
   The supplier is responsible for notifying GCM, ***prior to implementation***, of any desired or necessary change to the product, including the production process, manufacturing location or sub-supplier, when it is reasonable to conclude the change might affect product quality. GCM will evaluate whether the change affects the quality, reliability, safety, or efficacy of the finished product. If a drawing change is required, the Engineering Change Order (ECO) process will start, and the supplier will await a new drawing before proceeding with the change. Request for change should be done on form QAC-079 Quality & Engineering Communication.
   GCM will notify the supplier when and if the change has been approved. The supplier may be expected to provide supporting data and documentation to GCM as objective evidence. In any circumstance, the supplier must wait for approval from GCM before proceeding with the change.
4. **Communication**
   Date and quantity changes should be communicated through the buyer. Technical questions or improvement suggestions should be communicated to the applicable Project Engineer. If the applicable Project Engineer is not known by the supplier, then the communication should go through the buyer. Technical communication should be accompanied by form QAC-079 Quality & Engineering Communication.
5. **Competence**

The supplier must have a process for defining the jobs needs and ensuring that employees meet those needs through experience, training, or other reasonable method. Any specific qualification requirements will be communicated on the purchase order or part drawing.

6. **Awareness**

   The supplier must ensure that employees are aware of their contribution to product or service conformity, safety, and that ethical behavior is important.

7. **Conformance to Requirements**

   It is the supplier's responsibility to ensure all requirements are met before parts are shipped. Requirements include but are not limited to the purchase order, part specification, and all documents referenced on the PO. Where applicable, requirements of regulatory agencies, industry standards and supplier datasheets must be met.

   The supplier shall provide a Certificate of Compliance (C of C) with each shipment. The C of C shall document compliance to part specifications and all applicable regulatory and environmental requirements. Further requirements may be included in specific procurement specifications and documentation. In addition to the C of C, with the first shipment of each revision, the supplier shall provide supporting data to demonstrate first article (FA) acceptance to verify compliance with the part specification. Unless otherwise indicated in the procurement specification, all dimensional measurements shall be provided in the FA report.

   Suppliers must provide notification of nonconforming processes, products, or services and obtain approval for their disposition. For clarification of requirements or to request shipment of nonconforming material, form QAC-079 Quality & Engineering Communication may be required. Any shipment of nonconforming or potentially nonconforming material must be segregated and conspicuously marked with red tag, tape, sticker, or removable paint.

8. **Counterfeit Parts Prevention**

   A counterfeit parts prevention program is required when the PO specifies the requirement. The counterfeit prevent program should consider AS9100D and AS6174.

9. **Record retention**

   The supplier shall ensure all records related to the design & procurement, manufacturing, services and delivery of parts supplied to Creation are maintained for a minimum of 15 years unless otherwise specified.
   All records shall be signed or marked in a traceable manner to an authorized supplier representative.

10. **Disposition of Records**

    After the expiration of the Records Retention period the following are requirements for disposition of all records:

    a. Paper Records: Disposition methods include burning in an industrial incineration facility, pulping, pulverizing, or shredding. High wet strength paper, paper mylar, durable-medium paper substitute, or similar water repellant papers are not sufficiently destroyed by pulping and require other methods such as shredding or burning.
    b. Electronic Records: Disposition methods include physical destruction of storage media such as by shredding, crushing, or incineration; high level overwriting that renders the data unrecoverable; or degaussing/demagnetizing.
    c. Non-Paper Media: For media such as audio tape, video tape, microforms, photographic films, etc., disposition methods include pulverizing, shredding, and chemical decomposition/recycling.
    d. Records shall not be buried since burying does not ensure complete destruction or unauthorized access.

e. Customer Records: If required by contract, GCM will notify customers of the customers record retention expiration. Customer can either take their records or request GCM to disposition them as per the above methods.
f. Where possible, recycling following destruction is encouraged.

11. Rights of access

GCM, its customers, and regulatory authorities have the right of access for on-site visits pertaining to product quality, on-time delivery, compliance audit, and/or regulatory audits. Access includes facilities, documentation, and records through all levels of the supply chain.

12. Performance

Supplier performance is monitored with defect levels in PPM and on-time delivery. Lot acceptance at receiving inspection and nonconformance found later in the process are included in the PPM calculation. GCM reviews data at least once per year and notifies specific suppliers of poor performance so that an improvement plan can be developed. Suppliers should strive to achieve 100% on-time delivery and 0 defects.

13. Customer directed sources

Sources for sub-tier supplier can be controlled by GCM and will be stated accordingly on the PO or part drawing. In these cases, the supplier must ensure that the GCM directed source is used.

14. Flow down of Requirements

Requirements that must be flowed down through the supplier's supply chain will be stated accordingly on the part drawing and or PO.

15. Quality Management System

Suppliers must have a systematic and structured approach to managing quality. ISO9001 is the recommended minimum requirement. If aerospace, medical, or other special Quality Management System certifications are required it will be specified on the part drawing or PO (and quote).

16. Returns

GCM will request return material authorization for defects deemed to be caused by the supplier. In certain cases, material may be returned to the supplier without a request and approval to return the material.

17. Corrective Action

Corrective actions can be issued for specific product quality issues or for chronic poor performance. GCM will issue the CAR to the supplier and specify key dates for containment, root cause analysis, and corrective action implementation. Default lead time is 1 day for containment, 10 working days for root cause analysis, and 40 working days for corrective action implementation. The supplier CAR process should follow an 8D format including problem statement, containment, correction, root cause analysis, corrective action, and verification.

18. Handling, packaging, and shipping

All material, parts, and assemblies shall be packaged and shipped so that both the containers and their contents arrive at their destination damage free. All material, parts, and assemblies shall be packaged so that they are protected from any abrasion, nicks, dents, or scratches. Materials, parts, and assemblies are separated by purchase order. Parts or materials that require special storage or handling conditions as defined by the procurement specification, by industry standards, or by the manufacturer's specification shall be stored, handled, and shipped accordingly.

19. Outside processing suppliers – additional handling, packaging and shipping

Operational controls are implemented to prevent mixing of parts. Counts should be confirmed at receiving and shipping, with any discrepancies in counts or purchase order reported to GCM. Any defective pieces must either be dispositioned by GCM or sent back with the shipment, clearly tagged and separated from the good pieces. Unless otherwise instructed in writing,

completed parts should be packed in the same manner as GCM shipped them. Packaging must prevent spills or mixing of lots.

20. Legibility of Quality Records

All Quality Records/Certification must be legible and readily identifiable. Changes to records must remain identifiable (minimum who made the change and change date).

21. Restricted Materials

Materials provided to GCM must be RoHS compliant and REACH compliant. Meaning that they do not contain substances restricted by RoHS or that are on the REACH substances of very high concern list. Exceptions may be granted and will be expressly stated on the GCM purchase order.

5.0 Human Rights and Labor Practices

To ensure respect of all internationally proclaimed human rights by avoiding causation of and complicity in any human rights violations, heightened attention shall be paid to ensuring respect of human rights of specifically vulnerable rights holders or groups of rights holders such as women, children or migrant workers, or of (indigenous) communities.

1. **Prohibition of Forced Labor**
   Neither use nor contribute to slavery, servitude, forced or compulsory labor and human trafficking.
2. **Prohibition of Child Labor**
   Employ no workers under the age of 15 or, in those countries subject to the developing.
   country exception of the ILO Convention 138, employ no workers under the age of 14.
   Employ no workers under the age of 18 for hazardous work according to ILO Convention 182.
3. **Non-Discrimination and Respect for Employees**
   Promote equal opportunities and treatment of employees, irrespective of skin color, race, nationality, ethnicity, political affiliation, social background, disabilities, gender, sexual identity and orientation, marital status, religious conviction, or age.
   Refuse to tolerate any unacceptable treatment of individuals such as mental cruelty, sexual harassment or discrimination including gestures, language and physical contact, which is sexual, coercive, threatening, abusive or exploitative.
4. **Working Hours, Wages & Benefits for Employees**
   Recognize the legal rights of workers to form or join existing trade unions and to engage in collective bargaining; neither disadvantage nor prefer members of employee organizations or trade unions.
   Adhere to all applicable working-hours regulations globally.
   Pay fair wages for labor and adhere to all applicable wage and compensation laws globally.
   In the event of cross-border personnel deployment, adhere to all applicable legal requirements, especially with regard to minimum wages.
5. **Health & Safety of Employees**
   Act in accordance with the applicable statutory and international standards regarding occupational health and safety and provide safe working conditions.
   Provide training to ensure employees are educated in health & safety issues.
6. **Grievance Mechanism**
   Provide access to a protected mechanism for their employees to report possible violations.

6.0 Environmental Protection

Act in accordance with the applicable statutory and international standards regarding the environment.
Minimize environmental pollution and make continuous improvements in environmental protection.

7.0 Fair Operating Practices

1. **Anti-Corruption and Bribery**
   Tolerate no form of and do not engage directly or indirectly in any form of corruption or bribery and do not grant, offer or promise anything of value to a government official or to a counterparty in the private sector to influence official action or obtain an improper advantage. This includes to renounce from giving or accepting improper facilitation payments.

2. **Fair Competition, Anti-Trust Laws and Intellectual Property Rights**
   Act in accordance with national and international competition laws and do not participate in price fixing, market or customer allocation, market sharing or bid rigging with competitors.
   Respect the intellectual property rights of others.

3. **Conflicts of Interest**
   Avoid and/or disclose internally and to GCM all conflicts of interest that may influence business relationships, and to avoid even the appearance thereof.

4. **Anti-Money Laundering, Terrorism Financing**
   Not directly or indirectly facilitate money laundering or terrorism financing.

5. **Data Privacy**
   Process personal data confidentially and responsibly, respect everyone's privacy and ensure that personal data is effectively protected and used only for legitimate purposes.

6. **Export Control and Customs**
   Comply with the applicable export control and customs regulations.

8.0 Responsible Minerals Sourcing

Take reasonable efforts to avoid in its products the use of raw materials which originate from Conflict-Affected and High-Risk Areas and contribute to human rights abuses, corruption, the financing of armed groups or similar negative effects.

9.0 Supply Chain

Use reasonable efforts to make its suppliers comply with the principles of this document and comply with the principles of non-discrimination with regard to supplier selection and treatment.

Supplier Requirements Acknowledgement Letter

GCM Medical & OEM
1350 Atlantic St, Union City
CA 94587

Dear Key Supplier,
GCM is committed to excel in all aspects of our business. To this end, GCM requires all key suppliers, contractors, and sub-contractors to acknowledge and agree to follow the policies set forth in the attached **QMS-102 GCM Supplier Requirements** document.

The **QMS-102 GCM Supplier Requirements** document is intended to set guidelines for a good business relationship. The document is also used to flow specific requirements of GCM's customers throughout the supply chain.

By signing and returning an electronic or hard copy, the authorized representative of the below named Company (Suppliers) acknowledges awareness and acceptance of the **QMS-102 GCM Supplier Requirements.**

By: _____ _____

(Signature of Authorized Representative) (Date)

_____ _____

(Printed Name of Authorized Representative) (Title of Authorized Representative)

_____ _____

(Telephone Number) (Print Full Company Name)

_____

(Company Address)