



Supplier Quality Clauses

Document Number

SC2001

Revision: B

DCO1131 – Release Date 05/30/2023

Originator: Eduard R Vitale

Process Owner: Quality

Page 1 of 8

Clause	Responsibilities
1	<p>CERTIFICATE OF CONFORMANCE (C of C)</p> <p>All of C of C's for build to print part numbers must contain as a minimum, a generic statement indicating that the material supplied meets the requirements stated within the applicable purchase order.</p> <p>SELLERs are required to retain C of C's and all relevant data supporting build on file for a minimum of 10 years after completion of the subject purchase agreement.</p> <p>SELLER shipping documentation shall include as a minimum:</p> <ul style="list-style-type: none"> • BUYER Purchase Order number • BUYER Part Number and Revision • Serial number, or lot number, or date code <p>Material supplied for this contract shall be accompanied by a Certificate of Conformance (C of C) or Certificate of Analysis as follows:</p> <p>A. C of C's for make to print orders.</p> <ol style="list-style-type: none"> 1. The OEM's name. 2. Must include P/N, Revision, serial number (or lot number, or date code). 3. Signed C of C from the OEM. 4. The distributor packing slip and the OEM C of C must be linked to demonstrate traceability. (The packing slip from the Distributor may be used to link traceability). <p>B. C of C's for Commercial Off The Shelf (COTS) parts</p> <ol style="list-style-type: none"> 1. OEM C of C (no signature required). 2. OEM's name: A computer generated C of C is acceptable 3. Must include Manufacturer name, Manufacturer part number, and lot number or date code. 4. For Franchised Distributors, OEM C of C not required for shipments, however, supplier must retain on file for a minimum of seven (7) years. <p>C. C of A (Certificate of Analysis) for Materials Chemical Composition</p> <p>Chemical materials purchased for production related purposes must be accompanied by C of A include:</p> <ul style="list-style-type: none"> • Manufacturer P/N, Revision, serial number (or lot number, or date code, or batch number). • Date of expiration and/or Date of manufacture. • OEM's name. <p>D. Customer Supplied C of C</p> <ol style="list-style-type: none"> 1. Must include P/N, Revision, and serial number (or lot number, or date code) OR Correspondence from the Customer directing BUYER to use the supplied material for the intended production purpose and alleviating BUYER from traceability responsibilities.
2	<p>Supplier Approval</p> <p>Suppliers initially approved via Certification (ISO9001, ISO13485, ISO 17025, etc.) must notify our organization of any changes to that certification and provide updated certs upon expiration.</p>



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Page 2 of 8

Clause	Responsibilities
3	<p>QUALITY SYSTEMS</p> <p>The material supplied on this contract must be controlled under Genesis Medical Plastics Quality System, which can be one or more of the following: ISO 9001(latest rev) ,ISO 13485, (latest rev) ISO 14001(latest rev). Refer to our website for the latest revision of this document.</p>
4	<p>INSPECTION</p> <ol style="list-style-type: none"> 1. All articles and materials will be subject to inspection and approval by BUYER after delivery not withstanding prior payment. It is agreed that payment shall not constitute final acceptance. 2. Defective material or items not in accordance with BUYER's specifications will be held for Seller's instruction. If Seller directs, materials will be returned at Seller's expense. 3. No goods returned as defective shall be replaced without authorization from Buyer.
5	<p>DRAWINGS / SPECIFICATIONS & CHANGE CONTROL</p> <ol style="list-style-type: none"> 1. BUYER shall supply Seller with current drawings / specification required to fulfill this order. 2. BUYER reserves the right at any time to make changes in drawings and specifications as to any material and/or work covered by this order. SELLERs or their subcontractors are required to conform with all specifications included or referenced in this order. 3. Any components and /or materials that are being procured by BUYER in which a change by the vendor is in process, the vendor is required to notify BUYER prior to the change. <ol style="list-style-type: none"> a. This change notification requirement applies to any major changes that require customer or regulatory approval that may affect fit, form or function, design intent, materials, process and programming according to the applied quality standard. 4. All requests for Deviations and/or waivers from the SELLER shall be forwarded to the applicable BUYER. <ol style="list-style-type: none"> a. Notification of Facility Change: SELLER shall not use or relocate any production, manufacturing, and/or processing facilities to differ from previous approval by BUYER, during the performance of work specified in the procurement document, without previously notifying BUYER. b. Notification of change of product, process and/or sub-tier SELLER: SELLER shall not change any drawing, process, material (including sub-tier SELLER parts), without prior BUYER written approval, if such a drawing, process, material, or procedure was previously approved by BUYER as provided in the procurement document. c. Verbal changes are not acceptable. All product changes must be completed by an engineering change order approved by BUYER. Changes within a purchase order/agreement, whether the change is quantity, price or specifications, must come from BUYER and be reflected on the purchase order. 5. the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements"



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Revision: B

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Page 3 of 8

Clause	Responsibilities
6	<p>NON-CONFORMING MATERIAL</p> <p>1. Any departure from drawings, specifications or other Purchase Order requirements must be presented to BUYER for disposition. BUYER's customers must approve deviations from drawings or specifications prior to shipment of materials/product from SELLER's facility.</p> <p>2. Nonconforming material will not be accepted by BUYER unless approved in advance in writing by BUYER and with concurrence from BUYER's Quality Assurance Management Designee.</p> <p>3. Requests for authorization to ship nonconforming material will be addressed in writing to the appropriate BUYER Quality Assurance Department with full explanation of the nonconformance per SELLER's nonconformance reporting system.</p> <p>4. SELLER shall notify BUYER upon the discovery of a material discrepancy which was made from a material lot that has already been shipped to BUYER.</p>
7	<p>DOCUMENTS / DATA RETENTION</p> <p>1. Unless otherwise specified in purchase order, The SELLER shall retain objective written evidence of conformance to the Purchase Order requirements for each shipment for a period of 10 years. This shall include as applicable: Manufacturing Traveler, Manufacturing's Documentation, Tests, Engineering Change Orders and Inspection Documentation as applicable.</p> <p>a. Recorded data shall include not only the results of all routine inspections and Dimensional Data Reports, along with all required tests results such as Conditioning, Lot Acceptance, Sampling and Inspection documents or any other test used to determine item conformance.</p> <p>Note: The SELLER upon request of BUYER shall provide requested reports as part of the make to print order parts Documentation Data Package supplied with shipped product.</p> <p>b. If the SELLER is a jobber or distributor of the item(s) in this Purchase Order, the Seller shall require the same performance documentation from the original manufacturer of the item(s). Additionally, SELLER shall secure from that manufacturer a right for BUYER to acquire or inspect (at BUYER's option) all pertinent data in that manufacturer's possession showing the items' compliance to specification.</p> <p>c. The exact format of the submitted data may vary from Seller to Seller, but shall contain the following minimum information:</p> <ul style="list-style-type: none"> i. SELLER 's name ii. SELLER 's Purchase Order number and revision iii. BUYER Buyer's part number and Purchase Order number and revision iv. BUYER Drawing/specification/SELLER planning revision level v. Number of items in a lot vi. Number of items inspected vii. Acceptable Quality Level (AQL) used viii. Lot number and date code (if applicable) <p>d. The SELLER may obtain attributes data or variable data at Seller's discretion unless the variables data is specifically requested by the Buyer. The Seller's format is acceptable as a minimum attributes.</p>



Supplier Quality Clauses

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Process Owner: Quality

Page 4 of 8

Clause	Responsibilities
8	<p>PERISHABLE / SHELF LIFE MATERIALS</p> <ol style="list-style-type: none"> Any product, substance or material that has a limited life shall have a minimum of 50% of its certified shelf life remaining upon delivery to BUYER Engineering. The limited life period shall be identified on the product or support documentation. An SDS Sheet is to be provided with each shipment of product. The SELLER shall include the date of manufacture. The SELLER is responsible for maintaining the actual test data for a minimum of 10 years. Test data shall be made available upon request. A signed copy of the original material manufactures Certificate of Compliance must be provided with each receipt.
9	<p>CRITICAL CHARACTERISTICS IDENTIFICATION</p> <ol style="list-style-type: none"> When applicable, BUYER Engineering drawings and specifications will annotate critical characteristics exhibited by a symbol noted within the drawing legend or notes. The SELLER must make provisions within their processes to assure that all requirements identified as a critical characteristic are in compliance and must provide documentation in the form of variable data unless specified otherwise.
10	<p>FIRST ARTICLE INSPECTION (FAI) REPORT</p> <ol style="list-style-type: none"> SELLER shall perform a First Article Inspection that is applicable to all parts and assemblies with the exception to Commercial Off Shelf (COTS) parts. SELLER shall perform a full FAI or a partial FAI for affected characteristics, when any of the following occurs: <ol style="list-style-type: none"> First time delivery of the product. A change in the design characteristics affecting fit, form, or function of the part. A change in manufacturing source(s), process(es), inspection method(s), location of manufacture, tooling, or materials that can potentially affect fit, form, or function. A change in numerical control program or translation to another media that can potentially affect fit, form, or function (revision change). A natural or man-made event, which may adversely affect the manufacturing process. An implementation of corrective action required to complete a previous FAI. A lapse in production for two years shall require an update for any characteristics that may be impacted by the inactivity. This lapse is from the completion of last production operation to the actual restart of production. FAI reports shall be provided to the BUYER retained by the SELLER for a minimum of 10 years. Dimensional reports and drawing bubble diagrams are required when applicable.
11	<p>SINGLE LOT TRACEABILITY</p> <p>Items provided in accordance with this purchase order are under Single Lot Traceability Control at BUYER.</p> <ol style="list-style-type: none"> When the SELLER combines multiple lots of material in one container, this material shall be segregated and identified such that all material lot numbers are segregated and identifiable.



Supplier Quality Clauses

Document Number

SC2001

Revision: B

DCO1131 – Release Date 05/30/2023

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Process Owner: Quality

Page 5 of 8

Clause	Responsibilities
12	<p>CLEANLINESS</p> <ol style="list-style-type: none"> 1. Material supplied shall be free of foreign objects. 2. The material supplied on this purchase order shall be manufactured in an environment that is free of foreign objects.
13	<p>FRAUD OR FALSIFICATION</p> <p>Any knowing and willful act to falsify, conceal, or alter a material fact, or any false, fraudulent or fictitious statement or representation in connection with the performance of work under this purchase order may be punishable in accordance with applicable Federal Statutes.</p>
14	<p>FINAL SOURCE INSPECTION</p> <ol style="list-style-type: none"> 1. If BUYER Source Inspection (NSI) is required at the SELLER's facility prior to shipment of this order. Test and inspection data demonstrating conformance to the lot acceptance requirements as specified in the drawing or specification shall be generated and be ready for review. In addition, the SELLER shall furnish the necessary facilities, equipment, documentation and personnel in support of this inspection. 2. The SELLER shall notify BUYER a minimum of ten (5) working days prior to the material being ready for any identified inspection points. Final acceptance shall be at final destination. 3. BUYER reserves the right to waive the requirement for NSI. If NSI is waived, a copy of the waiver must accompany the shipment. Failure to include the waiver is cause for rejection. The quantity of pieces shipped must match exactly the quantity on the waiver. 4. BUYER Source Inspection shall be noted as a line item on the purchase order as applicable. 5. Acceptance of products at BUYER source inspection does not relieve SELLER of full specification compliance and purchase order requirements.
15	<p>CUSTOMER SOURCE INSPECTION</p> <ol style="list-style-type: none"> 1. BUYER customers reserve the right to waive this inspection. 2. Authorization to continue processing of material, less this inspection, will be to the SELLER from BUYER/ Quality Management provided in writing. 3. Documented evidence of source inspection/s or direction to waive agreed upon inspection(s) is to be provided with each shipment of associated product. 4. When applicable, BUYER may require Source Inspection from BUYER Customers. In such cases BUYER will coordinate with the SELLER in advance as to what Customer Source Inspection requirements are applicable. 5. The SELLER shall notify BUYER a minimum 5 days in advance of when material will be ready for Customer Source Inspection.
16	<p>FLOWDOWN TO SUB-SUPPLIERS</p> <ol style="list-style-type: none"> 1. SELLER shall flow-down to Sub-Tier Suppliers the applicable requirements as required by the purchase order either specifically or by reference. 2. This also includes any special provisions noted on the purchase order (including Quality Clauses) or other procurement documents, drawings, specifications, quality system requirements, regulations, public laws and other requirements as may be specified on the purchase order.



Supplier Quality Clauses

Document Number

SC2001

Revision: B

DCO1131 – Release Date 05/30/2023

Originator: Eduard R Vitale

Process Owner: Quality

Page 6 of 8

Clause	Responsibilities
17	<p>MARKING & IDENTIFICATION</p> <ol style="list-style-type: none"> The vendor is required to reference BUYER part number, revision, purchase order number, lot number or batch code on all labels and documents. Buyer part number shall be clearly on bags, intermediate and shipping boxes / containers.
18	<p>STATEMENT OF WORK (SOW)</p> <p>When specified on Genesis Medical Plastics purchase order. Items / material shall be subject to additional requirements per the SOW. Items that do not comply with stated SOW requirements shall be rejected by Genesis Medical Plastics</p>
19	<p>CORRECTIVE ACTION</p> <ol style="list-style-type: none"> When applicable, corrective action may be required for any non-conforming/failure mechanisms. A corrective action plan detailing the proposed permanent corrective actions shall be submitted and implemented within the specified time given in BUYER's SELLER Corrective Action Request (SCAR). <ol style="list-style-type: none"> The BUYER can provide their corrective action request form as well. Consequences may be imposed due to the SELLER's repeated lack of timely response which may include downgrading the Approved Vendor Listing (AVL) status and/or removal from the AVL.
20	<p>CALIBRATION SYSTEM REQUIREMENTS</p> <ol style="list-style-type: none"> Test and measurement tools / equipment used to determine the acceptability of delivered items shall be maintained in accordance with ANSI/NCSL Z540-1, "Calibration System Requirements" or an equivalent specification. The SELLER shall maintain a calibration system that complies with MIL-STD-45662, ISO 10012 or ISO 17025 requirements.
21	<p>PACKAGING REQUIREMENTS</p> <ol style="list-style-type: none"> SELLER shall have a system for controlling and monitoring proper handling, preservation, storage, packaging, and shipping processes to protect the quality of deliverable materials and to prevent their damage, deterioration and degradation. The packaging material shall not in any way affect the quality of the product. When multiple separate packages/containers are delivered as part of a shipment or an order fulfillment of a single PN, each bag shall be marked/labeled with the following content information: <ol style="list-style-type: none"> Part Number Quantity per bag/container Date code(s) in bag/container Bulk Pack: Appropriate material shall be inserted into the intermediate container to prevent damage during shipping / handling / storage, as required. Lot Identification: Items furnished under this Purchase Order shall be identified by SELLER identification code and manufacturing lot or batch number on the package as applicable.



Supplier Quality Clauses

Document Number

SC2001

Revision: B

DCO1131 – Release Date 05/30/2023

Originator: Eduard R Vitale

Process Owner: Quality

Page 7 of 8

Clause	Responsibilities
22	<p>1. COUNTERFEIT GOODS</p> <p>SELLER represents and warrants that it will not knowingly or negligently use or procure counterfeit components in the Product or as replacement components.</p> <p>a. "Counterfeit Goods" as used in this Agreement means Product or components thereof that are or contain items misrepresented as having been designed and/or produced under an approved system or other acceptable method, including any of the following:</p> <ul style="list-style-type: none"> (i) an unauthorized copy or substitute of an Original Equipment Manufacturer or Original Component Manufacturer (collectively, "OCM") item; (ii) not traceable to an OCM sufficient to ensure authenticity in OCM design and manufacture; (iii) do not contain proper external or internal materials or components required by the OCM or are not constructed in accordance with OCM design; (iv) have been re-worked, re-marked, re-labeled, repaired, refurbished, or otherwise modified from OCM design but are represented as OCM authentic or as new; or (v) have not passed successfully all OCM required testing, verification, screening, and quality control processes.
23	<ul style="list-style-type: none"> (vi) SELLER will ensure the Product furnished to BUYER is not Counterfeit Goods. (vii) SELLER will ensure that Counterfeit Goods are not delivered by ensuring the direct procurement of items from OCMs or authorized SELLERs, and, when items are to be procured from non-authorized SELLERs, obtaining from such non-authorized SELLERs appropriate certificates of conformance that provide one or more of the following: <ul style="list-style-type: none"> a. The OCM's original certificate of conformance for the item (per Quality Clause #1, b. Sufficient records providing unbroken supply chain traceability to the OCM; c. OCM's test and inspection records demonstrating the item's authenticity. In all cases, prior to procurement from non-authorized Sellers, SELLER must contact BUYER for written approval, and the parts must be controlled such that BUYER will have unambiguous insight into the origination, control and where applicable serial number of all components. <p>b. Counterfeit Goods delivered or furnished to BUYER under this contract are deemed nonconforming.</p> <p>c. If SELLER becomes aware or suspects that it has furnished Counterfeit Goods to BUYER, SELLER will immediately notify BUYER.</p> <p>d. If SELLER has met the conditions of (a) and (b) noting the approval process for non-authorized SELLERs, then both parties will mutually share in the expense and replace such Counterfeit Goods with OCM or BUYER-approved Product that conforms to the requirements of this Agreement.</p> <p>e. If SELLER has not met the conditions of (a) and (b), then SELLER shall be liable for all reasonable costs related to the replacement of Counterfeit Goods and any testing or validation necessitated by the installation of authentic Product or components after Counterfeit Goods have been replaced.</p> <p>f. The remedies contained in this article are in addition to any remedies BUYER may have at law, equity, or under other provisions of this contract.</p>



Supplier Quality Clauses

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Process Owner: Quality

Page 8 of 8

g. BUYER becomes aware that counterfeit parts have been provided by SELLER, BUYER shall notify SELLER of the situation as soon as practical. In such case, SELLER shall be responsible as described in paragraph (a) above without right to offset by Section (b) and (c).

2. SELLER of Electronic parts for Aerospace devices will follow and apply the Counterfeit Electronic Parts Avoidance, Detection, Mitigation and Disposition standards AS5553

3. COUNTERFEIT AVOIDANCE TESTING (SAE AS6081)

a. If required, SELLER is 100% responsible for the compliance of this testing requirement prior to delivery to BUYER.

b. SELLER shall supply documentation demonstrating compliance and maintain the records per the Document / Data Retention quality clause defined herein (as applicable).

c. Verification of procured product shall be performed per SAE AS6081 Table 1.

d. In the event that the components are found to be defective and it cannot be demonstrated that SELLER was in conformance with the purchase order test requirements, BUYER shall have the right to reject them.

e. The report provided after testing must itemize each item from the test requirements with reference to the number of samples tested and the results of these tests.

f. Test facilities are required to report the discovery of Counterfeit Components per the SAE AS6081.

CONFLICT MINERALS (Dodd-Frank Compliance)

The term "conflict minerals" is defined as columbite-tantalite (coltan), cassiterite, gold, wolframite, tantalum, tin, tungsten, and any other mineral or its derivatives.

The rule requires tracing of conflict minerals through supply chains to determine and disclose whether the raw materials originate at mines in the Democratic Republic of the Congo (DRC) or its nine adjoining countries.

The law requires U.S. manufacturers and retailers to monitor their supply chains in an effort to curtail human rights abuses in Africa where the raw materials are mined.

24