



Supplier Quality Clauses

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- 1) Upon acceptance of a Genesis purchase order, the Supplier agrees to supply products and services to the specifications within our purchase orders.
- 2) Any deviations from the purchase order requirements, whether technical or delivery delays, are to be communicated in a timely manner back to Genesis.
- 3) Our organization reserves the right of final approval of products, procedures, processes, equipment, and Supplier Quality Management System.
- 4) All special processes (processes where the required output cannot be verified non-destructively) required by this PO must be performed by qualified personnel within a validated process.
- 5) Suppliers initially approved via Certification (ISO, ISO 17025, etc.) must notify our organization of any changes to that certification.
- 6) Our organization reserves the right to approve or specify any designs, tests, inspection plans, verifications, use of statistical techniques, etc., for product acceptance.
- 7) Supplier shall allow Genesis Medical Plastics Ltd Co., our customers, and regulatory agencies the "right of access" to any place necessary to determine and verify the contracted work conforms to specified requirements, including all applicable records and materials.
- 8) The Supplier is required to:
 - a) Maintain the proper identification and revision status of specifications, drawings, process requirements, inspection/verification instructions, and other relevant technical data.
 - b) Ensure all products that do not conform to the Genesis requirements (nonconforming product) are identified and controlled to prevent their unintended use or delivery. Obtain Genesis approval for dispositioning nonconforming product for use as-is.
 - c) Maintain a consistent process in which to make Genesis products and/or render services to Genesis.
 - d) Notify our organization of changes in product and/or process, changes of suppliers, and changes of manufacturing facility locations.
 - e) Planned changes that may affect the product or services (including those listed in 8d) are to be approved by Genesis before changes are made.
 - f) Flow down to the supply chain the applicable requirements including customer requirements.
 - g) Provide root cause analysis, effective corrective and preventive action as requested.
 - h) Retain all records associated with the Purchase Order for 10 years or as required by contract. If for any reason, the company decides to dispose of these records prior to the required time frame, the company is to provide the opportunity for Genesis to retain these records.
- 9) CALIBRATION
 - a) All suppliers providing Calibration Services must be accredited in accordance with ISO17025 (or equivalent). All Calibration Certificates must identify standards used and must be traceable to NIST (National Institute of Standards Technology).
 - b) Supplier shall maintain a documented calibration system for the control and maintenance of measuring and test equipment.
- 10) Certification of Materials and/or Process performed must accompany materials/parts received as requested.
- 11) EXPORT/IMPORT
 - a) Information may be furnished to supplier containing data subject to U.S. Export Laws and Regulations. Supplier is advised that such data may not be exported to foreign persons, employed by or associated with, or under contract to supplier or supplier's lower-tier suppliers, without prior written consent.
- 12) COUNTERFEIT PARTS PREVENTION
 - a) The Supplier warrants that Counterfeit Supplies shall not be supplied to the Purchaser or installed in the Purchaser's products by the Supplier.
- 13) PERFORMANCE
 - a) All external providers to Genesis Medical Plastics Ltd Co. must be aware of the importance of their contribution to product and service conformity, their contribution to product safety, and the importance of ethical behavior.
 - b) Suppliers are measured and monitored according to: on-time delivery, product conformity, and responsiveness in order to ensure acceptable performance. Suppliers that consistently have an unsatisfactory rating may be removed from the Approved Supplier List.
- 14) CODE OF ETHICS
 - a) Supplier shall conduct all business affairs according to the highest standards of business ethics and integrity.