QUALITY REQUIREMENTS FOR PURCHASED GOODS AND SERVICES

As noted in Ultralife Corporation (Ultralife) Terms and Conditions for Purchase Orders, acceptance of an Ultralife Purchase Order (PO) constitutes acknowledgement that the Seller has read, understands and will comply with the quality requirements described in the current version of this document. Delay or failure by Ultralife to confirm supplier's conformance with these requirements shall not constitute a waiver of Ultralife's rights hereunder or under any supply agreement or PO corresponding to these quality requirements, or acceptance of any modification of them.

A. Purpose and Scope

This document has been developed by Ultralife to clearly communicate quality requirements to all new and existing suppliers, including raw material and component suppliers, original component manufacturers (OCM), original equipment manufacturers (OEM), contract manufacturers of finished devices, printed materials and service suppliers. These quality requirements shall apply to the development and manufacture of all goods and services supplied to Ultralife.

Quality requirements may take the form of a separate quality agreement, or an exhibit or addendum to, or content in a PO or other agreement. They also encompass the requirements set forth in this document as well as in other technical documents corresponding to a PO or other agreement, such as engineering specifications.

The requirements within this document are provided as a supplement, not as a replacement for or modification of the terms or conditions covering pre-established agreements, engineering drawings, or specifications. If conflicting interpretations of the standards arise, the following order of precedence applies unless otherwise noted contractually:

1. Agreements (Quality, Supply, or other written agreements).
2. Specification Requirements.
3. Ultralife Purchase Orders.
4. Quality Requirements Document.

B. General Supplier Responsibilities

Suppliers are responsible for ensuring that goods and services supplied meet established Ultralife specifications and quality requirements. Audits, approvals, verification or knowledge by Ultralife of the supplier's facility, quality system, process controls, acceptance activities, or other procedures does not absolve the supplier of the responsibility to provide acceptable goods and services; nor will it preclude the subsequent rejection of unacceptable goods and services. In considering the requirements in this document, it is important to note the following terms:

- Should, May, Expect – Action is strongly recommended.
- Must, Will, Shall – Action is required.

C. Quality Management System (QMS)

Suppliers are required to establish, document, and implement an effective QMS. The supplier will ensure that the quality requirements in this document are thoroughly distributed, understood, and maintained, and that adequate levels of authority have been established to ensure the continuous improvement of the QMS.

QMS expectations are dependent on the supplier type and category, as outlined in the following table. For existing suppliers that are not registered to the indicated ISO standard, it is strongly suggested that they have or put a plan in place to become registered and can demonstrate progress toward that plan.

Supplier Type	Minimum Requirements	Preferred Requirements
Custom Raw Material, Component and Component Services	Demonstrated Quality Assurance/Control System (see Appendix A and B as appropriate).	Quality System that demonstrates conformity with ISO 9001:2015 or ISO 13485:2016 (for drawings of parts that subsequently go into a medical device as stated on part drawing).
OEM and Contract Manufacturing of Finished Devices	Quality System that demonstrates conformity with ISO 9001:2015 or ISO 13485:2016 (for drawings of parts that subsequently go into a medical device as stated on part drawing).	Quality System that is registered to ISO 9001:2015 or ISO 13485:2016 (for drawings of parts that subsequently go into a medical device as stated on part drawing).

Note: Distributors are exempt from these requirements and shall maintain an approved and/or qualified manufacturers list.

Suppliers that are ISO-registered must notify Ultralife in writing within five (5) business days if their quality management system registration is suspended, placed on probation, expired, or if the supplier has been placed on any special status with their customers or registrars due to quality or delivery issues. New or updated quality management system registration(s), in instances where there are mergers, acquisitions, or affiliations associated with suppliers, shall be provided to Ultralife within ten (10) business days from receipt of the new registration certificate. Ultralife and its customers reserve the right to verify conformance of supplier's quality management system to the ISO standard. Upon request, suppliers shall forward evidence of their quality management system registration to Ultralife.

D. Non-Disclosure Agreements

Suppliers to Ultralife may be asked to sign a non-disclosure agreement (NDA), depending on the level of technology or information disclosed during business. It is Ultralife's policy to utilize its standard form, created for this purpose. Information provided to suppliers involving various trade secrets, designs, materials and other proprietary information of a secret and confidential nature may include, but are not limited to records, data, schedules, forecasts, formulae, commercial information, processes, procedures, specifications, developments, designs, inventions, models, techniques, improvements or discoveries, patentable and otherwise.

Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of its non-disclosure or any other written agreement with Ultralife. Suppliers shall not make any public announcement about or advertise the existence of this agreement, divulge its terms and conditions or any relationship with Ultralife, other than with prior written agreement by Ultralife. Suppliers shall agree not to display or use the Ultralife logo, trade secrets, trademark, or product(s) in any manner without our prior written permission from their Ultralife supply chain representative.

E. Sub-Tier Supplier Control

It is the supplier's responsibility to ensure and control the quality of all components and raw materials that are purchased to manufacture goods for Ultralife. Suppliers will manage sub-tier suppliers with quality controls commensurate with those required by Ultralife. Suppliers are responsible to ensure that goods manufactured utilize only authentic, conforming and specified components and materials, as stipulated in the Bill of Materials (BOM) and sourced from OCM/OEM; OCM/OEM-franchised distributor; or, with prior written authorization from the customer, or designated third parties. (See Definitions below.)

Definitions:

OCM – Original Component Manufacturer

OEM – Original Equipment Manufacturer

Franchise Distributor – A distributor with whom the OCM has a contractual agreement to buy, stock, repackage, sell and distribute its product lines. Franchised distributors normally offer product for sale with full manufacturer's warranty. Franchising contracts may include clauses that provide for OCM's marketing and technical support, failure analysis and corrective action, and exclusivity of inventory.

Independent Distributor (Broker) – A 3rd party distributor that purchases parts with the intent to resell them. These distributors may be franchised for selected, but not all, product lines. For purposes of counterfeit risk mitigation, a distributor is considered independent when not franchised for the item to be procured.

F. Surveys and Surveillance Audits

Ultralife, Ultralife's customer, and governmental and/or regulatory authorities have the right to conduct surveys and surveillance audits of the supplier's facilities with prior coordination with supplier, to determine the capability of the supplier to comply with and to verify continuing compliance with the requirements of the respective PO.

G. Change Management

Suppliers shall immediately notify Ultralife via a Supplier Support Request (SSR) form FA02500 (available upon request) when initiating a change to purchased goods and services. Ultralife requires a minimum of ninety (90) days notification of change; and 180 days in the case of changes where a manufacturing line shut-down or relocation is involved. Suppliers shall not implement any such change without Ultralife's prior written consent; and shall ensure that sub-tier suppliers follow this same procedure.

Ultralife personnel shall review and approve supplier-initiated changes to purchased goods and services, including without limitation:

- changes to components, materials or chemical composition.
- updates to component or product specifications; new or alternate sub-tier suppliers.
- changes to product design, labeling, packaging or product part number.
- supplier name or address changes.
- relocation of manufacturing equipment, including without limitation, within the same facility, facility to facility transfer of manufacturing processes or technology, altering environmental specifications or conditions in areas used for manufacturing, storage, or testing.
- process changes, including new equipment, modifications to existing manufacturing, test or inspection equipment, qualification/validation of new or existing equipment and transitions from manual to automated processes.
- In-process and final acceptance test changes (e.g. test specification, test application, validation, outgoing inspection plan and/or test acceptance requirements).

Suppliers must submit proposed changes to Ultralife in writing. The information provided must, at a minimum, include a complete description of the change and an initial assessment of the impact of the proposed change on the goods or services to be delivered.

Upon request, the supplier shall submit prototype samples with the proposed changes for evaluation and analysis by Ultralife, third parties, or downstream customers to test concept.

Suppliers must complete all verification and testing to ensure that modified processes continue to yield goods that meet specification. Written approval from Ultralife is required prior to full implementation of the requested change and subsequent delivery.

H. Measuring and Test Equipment

The supplier shall be responsible for validating the accuracy and stability of tools, gauges, and test equipment used to demonstrate that items conform to the PO. Traceability of calibration equipment and gauges shall be to international or national measurement standards such as the National Institute of Standards and Technology (NIST) unless stated otherwise in the PO. Documented schedules shall be maintained to provide for periodic calibration to adequate standards. Objective evidence of calibrations shall be recorded and made available for Ultralife review.

I. Process Control and Measurement System Analysis (MSA)

For those characteristics specified by Ultralife, suppliers may need to perform a gauge correlation study. Suppliers shall develop or obtain gauges to control their processes and inspect manufactured goods. When feasible, gauges used to inspect parts should be variable gauges, which have been designed to inspect the functionality of the part. If variable gauges are not available, then attribute gauges ("go" or "no go") are acceptable for use, with the approval of Ultralife.

Suppliers shall consider Measurement System Analysis (MSA) in determining whether measurement or test equipment has enough accuracy, precision or resolution to adequately provide information about process performance.

When required by Ultralife, suppliers must perform a Gauge Repeatability and Reproducibility (Gauge R&R) study. The Gauge R&R study should be developed using procedures described in Measurement Systems Analysis published by AIAG (Automotive Industry Action Group) or equivalent. Unless otherwise directed by Ultralife, a Gauge R&R study is required for all special characteristics. Studies using variable data are preferred, although attribute MSA is acceptable. Ideally, because of the MSA the total variations should be less than 10% of the tolerance.

J. Inspection Records and Shipping Documents

First Article Inspection (FAI)

When required by Ultralife, suppliers shall complete a First Article Inspection (FAI) report for each first time build and submit this report to Ultralife for review and acceptance. Any changes which alter form, fit or function require a revised FAI. The FAI shall be performed on single or multiple completed units, which are clearly identified as the "first article".

Certificate of Analysis (CoA)

When required by Ultralife, suppliers shall provide a written statement certifying materials comply with PO requirements based on quantitative instrumented physical or chemical analysis of representative samples taken from the shipment accompanying the certificate signed by an authorized representative of the supplier's company. The CoA shall include the part number, revision, Ultralife PO number, PO date and PO revision.

Certificate of Conformance (CoC)

When required by Ultralife, suppliers shall provide a written statement certifying that all product in the shipment accompanying the certificate complies with PO requirements, signed by an authorized representative of the supplier's company. The CoC shall include the part number, revision, Ultralife PO number, PO date and PO revision.

Shipping Documents

Supplier's shipping documentation shall clearly identify any shelf life requirements or maintenance requirements (such as charging of cells) for the parts or materials supplied.

K. Counterfeit Parts Prevention

When required by Ultralife on the PO, at a minimum, supplier shall have an electrical, electronic, and electromechanical (EEE) counterfeit parts prevention plan that incorporates the following:

1. Assesses potential sources of supply to determine risk of receiving counterfeit parts.
2. Maintains a register of approved suppliers, including the scope of the approval, to minimize the risk of counterfeit parts supply.
3. A documented process to specify contract/purchase order quality requirements to minimize the risk of being provided counterfeit parts.
4. A documented process, commensurate with product risk, to assure detection of counterfeit parts prior to formal product acceptance.
5. A documented process to assure that all occurrences of counterfeit parts are reported, as appropriate, to internal organizations, customers, government reporting organizations (e.g., GIDEP), industry supported reporting programs (e.g., ERAI), and criminal investigative authorities.

The supplier, and its' sub-tier suppliers, shall ensure that only new EEE parts\are used in products required to be delivered to the Ultralife. To further prevent the inadvertent use of counterfeit parts, the supplier may only purchase components and parts procured directly from the Original Component Manufacturers (OCMs), the Original Equipment Manufacturers (OEMs), or through the OCM/OEM's authorized distribution chain.

The supplier, and its sub-tier suppliers, shall not provide refurbished or used EEE parts unless first approved in writing by Ultralife through the request and approval of a Supplier Support Request (FA02500). The supplier, and its sub-tier suppliers, shall not provide items through a non-franchised distributor unless first approved in writing by Ultralife through the request and approval of an SSR.

The supplier shall provide full traceability identifiers (i.e., name and location of all supply chain intermediaries, date code/lot code, and serial number) for all items delivered to Ultralife which contain an item procured from sources other than OEMs, OCMs or their Authorized Distributors.

Supplier shall provide timely notification within ten (10) business days to Ultralife with the pertinent facts if it becomes aware that it has delivered fraudulent, suspect counterfeit, or counterfeit work to Ultralife.

Suspect counterfeit or counterfeit parts will not be returned to supplier nor reimbursed. Supplier shall at its expense promptly replace any suspect counterfeit or counterfeit parts with new parts conforming to the requirements of the PO. Ultralife will provide documentation to the supplier with results of investigation indicating suspect counterfeit parts and coordinate any supplier review of suspect counterfeit parts at the Ultralife's facility.

Supplier shall include flow-down of equivalent provisions in all lower tier procurements for items that will be included in items furnished to Ultralife.

L. Record Retention

Supplier shall retain documented information for parts and/or materials supplied to Ultralife for a minimum of 10 years after shipment, after which time the supplier may dispose of the documents in a manner maintaining record confidentiality. For parts that are intended to go into a medical device as stated on part drawing, the Supplier shall notify Ultralife Quality in writing at least ninety (90) days before destruction or disposal of any records and will instead transfer such records to Ultralife as directed at the request of Ultralife.

M. Packaging and Preservation

Boxes or containers, as applicable, should be selected to the extent necessary to provide protection from physical and environmental damage during shipping and handling. Cushioning materials shall be applied, as required, to protect and to restrict movement of the item(s).

Electrical components shall be kept from direct contact with cardboard and other paper products. Electrostatic Sensitive Discharge (ESD) components shall be labeled “ESD Sensitive” and/or be delivered in marked ESD-protective packaging in accordance with ANSI/ESD S20.20 or equivalent.

Perishable items or those with limited shelf life must be handled/preserved in accordance with recommendations of the manufacturer with shelf life marked on the item and shall have 75 percent remaining total available shelf life from the initial date of certification when received by Ultralife. The latest SDS/MSDS for all chemical shall be supplied to Ultralife upon request.

N. Reporting of Non-Conforming Material

The supplier named on the purchase order retains full responsibility for ensuring products or services furnished here under; comply with all applicable specification and standard requirements for design, construction, and workmanship.

Suppliers must maintain and implement a reporting process for products, articles, or services that have been released from or provided by the supplier and subsequently found not to conform to Ultralife’s requirements. Supplier must notify Ultralife in writing within two (2) business days of such a quality escape.

O. Return Material Authorization (RMA)

When requested by Ultralife, suppliers shall provide a Return Material Authorization (RMA) or a written justification for non-acceptance of a return to Ultralife within five (5) business days from receipt of the RMA request.

Unusual circumstances that require additional time to resolve should be arranged in advance by the supplier through Ultralife’s quality department.

P. Supplier Corrective Action Requests (SCAR)

When a quality problem exists with supplier’s items, Ultralife may forward a Supplier Corrective Action Request (SCAR) to supplier. Suppliers must provide a timely response by the due date on the SCAR; typically, within ten (10) business days from receipt of the SCAR, using the Ultralife SCAR form which includes:

- The short-term interim containment of suspect parts (if applicable).
- Analysis of the root cause of the problem.
- Identification of corrective action taken to prevent recurrence of the issue.
- Verification of effectiveness of the corrective actions taken.

Unusual circumstances that require additional time to resolve must be arranged in advance by the supplier through Ultralife’s quality department.

APPENDIX A: Minimum Requirements for a Manufacturer's "Demonstrated Quality System"

A1. Communication

Process(es) in place for customer and supplier communication, that includes handling of complaints and that allows for customer and/or regulatory audits (as appropriate).

A2. Employee Training

Process training in place for employees to minimize errors and improve productivity with a training record maintained in accordance with section L.

A3. Facilities, Machinery and Equipment

Process(es) in place for maintenance of all critical facilities, machinery and pieces of equipment. The Supplier shall provide and maintain gauges and other measuring and testing devices necessary to assure that supplies conform to the technical requirements and shall have process(es) to calibrate measuring equipment with traceability to NIST.

A4. Materials Controls

Process(es) in place to ensure capability of all suppliers with records maintained. Documented requirements for all incoming parts/materials. Process(es) such as incoming inspection and/or review of certificates to assure conformance of incoming parts/materials to documented requirements with a record maintained in accordance with section L. Control of shelf life materials and materials with storage requirements (temperature, humidity, etc.).

A5. Production and Process Controls

Documented training or work instructions for all employees having responsibilities for the operation of processes that impact conformity to product requirements that includes:

- Requirements Definition
  - critical product characteristics identified
  - specification/tolerance
- Identification and Traceability
  - lot/batch identification
- Methods
  - process parameters with process-related special characteristics identified
  - machines, jigs, fixtures, tools for manufacturing
  - evaluation measurement technique, sample size and frequency
  - rework and reverification
  - records

A6. Configuration Management including Change Controls

Process(es) to maintain control of internal and external documents and changes to them.

A7. Non-Conforming Material

Process(es) in place for segregating and reporting nonconforming incoming parts or materials and in-process or final rejected parts with defined, qualified personnel identified to disposition those nonconforming parts or materials.

A8. Corrective and Preventive Action (CAPA)

Process(es) in place to identify and contain issues, investigate the root cause, identify and assign responsibility for corrective actions.

APPENDIX B: Criteria for a Service Provider

B1. Knowledge

Experience matters; it is import they know what they are doing.

B2. Competitive Pricing

Get value for the money.

B3. Communication

Process(es) in place for customer communication, that includes handling of complaints and that allows for customer and/or regulatory audits (as appropriate).

B4. Adequacy of Resources

Ensure sufficient resources for period of the contract.

B5. Issue Resolution

Process(es) in place to resolve any issues encountered.