Approvals:

Management Representative

Department Manager / Process Owner

Revision History

Date	Change Notice	Change Description
9-9-2013	CN-2013-049	Original Release.

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1.0 Quality Requirements:

General Requirements applicable to all Purchase Orders:

1.1 Surveillance:

Controls For Automation (CFA) reserves the right to conduct periodic audits of the seller's Quality Assurance Inspection system and to witness and/or conduct inspections and tests to assure the suppliers materials or supplies satisfactorily meet procurement document requirements. This includes the review of corrective action activities and other Quality records that reflect on hardware or service quality.

1.2 Changes:

The Supplier shall not accept verbal changes to the specifications, drawings or Purchase Orders Requirements without supporting documents from CFA.

1.3 Discrepancies:

Any deviations from established drawing or specifications intended for shipment must be reported to CFA immediately.

No deviations will be considered approved without written confirmation from CFA.

Repairs are not to be undertaken without prior written approval from CFA unless otherwise specified within CFA's Purchase Order.

The Supplier and/or any of their Suppliers or Subcontractors do not have authority to process "USE-AS-IS", "REPAIR", "STANDARD REPAIR PROCEDURES (SRPS)" or "NON-SRPS" via their Material Review Board (MRB). These dispositions, as well as deviations and request for waivers, requiring MRB disposition shall be submitted to CFA for approval.

Note: This does not include REWORK or SCRAP.

The Supplier or Subcontractor shall utilize its appropriate nonconforming material disposition form and submit it to CFA for approval.

1.4 Corrective Action:

Acceptance of CFA's Purchase Order obligates the supplier to perform upon request a corrective action investigation when discrepant material is received at CFA. A written report shall be furnished, within a stipulated time period, which is specific and conclusive to prevent a recurrence of the discrepancy.

1.5 Documentation:

CFA shall not accept items delivered under the purchase order if the supplier fails to submit certifications or other documentation specified in the purchase order.

1.6 Preservation and Packaging:

The supplier shall use best commercial practices for preservation and packaging of articles supplied to CFA unless special packaging requirements are referenced in the purchase order.

The supplier shall identify each package with the purchase order number, date shipped and packing sheet number.

1.7 **Counterfeit Parts:**

CFA understands that counterfeit parts are a serious issue worldwide. Acceptance of this Purchase Order obligates the supplier to only send authentic parts. Any product that cannot be verified as authentic with the Manufacturer will not be returned to the seller but will be treated as counterfeit and governmental oversight will have final determination.

2.0 Medical Device Supplier Quality System Requirements / Clauses:

The following requirement / clauses become a part of the purchase order when specified by number or letter code on the Purchase Order.

2.1 **QSR1 – Quality System:**

The Supplier shall provide and maintain a quality system that complies with the requirements of ISO9001 or ISO13485, unless otherwise directed by CFA.

Immediate notification is required in the case of non-compliance to the quality system requirements. For example, loss of third party certification.

2.2 **QSR2 – Source Inspection:**

Source Inspections shall be conducted by CFA at the Supplier's facility or where designated in the Purchase Order prior to shipment.

Inspection/test of the purchased items shall be performed by the Seller and shall be subjected to witness by CFA. CFA shall elect to do 100% or sample inspection of the supplied units. The Seller shall have available and present upon request the documented evidence of in-process and/or final inspection/test data. The required documentation for shipment must be completed and signed by the suppliers Quality Assurance Manager or authorized designee and made available for CFA's review.

2.3 **QSR3 – Certificate of Conformance:**

The suppliers Quality Assurance Manager or authorized designee shall sign the products Certificate of Conformance (C of C) and the signed C of C shall accompany each shipment.

The C of C shall state that the product(s) supplied is in full conformance with all physical configuration and functional test specifications. That all raw materials used conforms to applicable specifications. If applicable, that the inspection, test data, physical and/or chemical analysis and in-process inspection data are on file and that they are subject to review by CFA upon request. The signed certificate of conformance shall be legible and include:

2.3.1 CFA's purchase order number, part number, and revision letter (unless otherwise specified on the purchase order),

2.3.2 Material or process specifications,

2.3.3 Quantity and if applicable, serial numbers and CFA's job/work order number and

2.3.4 Manufacturer's name, address, Country of Origin and Date.

When multiple lots of material are used in completing a shipment, the parts shall not be mixed and all material lot numbers shall be reported. When processing is performed against a CFA's job/work order, the parts shall not be mixed and traceability shall be maintained with the work order.

2.4 **QSR4 – Chemical and Physical Test Reports:**

Physical and chemical test report certifications shall be supplied with each shipment for raw material shipments or where materials are supplied to CFA by the supplier. Test reports shall be legible, signed and include the following:

2.4.1 Material designation, specification and revision letter. The material must be certified to the latest revision in effect at the time of shipment.

2.4.2 Results of all specified testing requirements and any other requirements specified on the purchase order and

2.4.3 They must be traceable to the material.

2.5 **QSR5 – Inspection Sheets and Test Reports:**

When specified, the supplier shall submit inspection reports, data sheets, test reports, etc… Reports shall be identified with the applicable drawing / specification number, revision, CFA's purchase order number, and the supplier's lot identification number.

A. Initial First Article Inspection reports shall cover and list all physical and dimensional characteristics for the item as called out on the drawing or within the applicable specification. The inspection results shall be traceable by serial number or other identification method to the actual part inspected.

B. Sample inspection shall be performed to verify critical dimensional characteristics of the parts to ensure that they are within drawing specification limits. Actual dimensions do not have to be reported except where specific dimensions are requested.

NOTE: Out of tolerance dimensions shall be identified on an inspection report. The supplier shall not deliver parts that are out of tolerance to CFA without approval from CFA.

2.6 **QSR6 – Record Retention and Right of Access:**

The Supplier shall retain all records pertaining to material, manufacturing processes, special processes, testing, and inspection for a minimum of:

- Non-Medical Device = three (3) years as applicable.
- Medical Device = ten (10) years as applicable.

The supplier shall provide CFA, our customers and regulatory authority access to all applicable records.

The Supplier shall notify CFA prior to the destruction of any Quality Records.

2.7 **QSR7 – First Article Inspection (FAI):**

The Supplier shall perform and document a comprehensive inspection and test of the article to assure the items conform to all specification requirements.

FAI's shall be performed in accordance with medical device standard ISO13485.

The FAI is required on a part representative of the production process to be used in the manufacture of these parts. A copy of the First Article document must accompany the first shipment of parts. If two years have elapsed since the last shipment of this part than a new First Article Inspection is required. If a 13485-compliant First Article Inspection Report (FAIR) is not required than an equivalent supplier FAIR form may be used and shall include the following:

2.7.1 Part number, revision level,

2.7.2 All print requirements including, Notes, Feature, Tolerance and

2.7.3 The actual measured value, Method of Gauging and Accept/Reject indication.

Where physical testing is required, the results of the test must be recorded.

Verification of each special process must be recorded, applicable certifications retained, and available for review (or submitted with the FAIR if requested by CFA) where special processes are required.

The signature and title of the person performing the inspection and the date of inspection must also be included.

2.8 **QSR8 – Survey / Audit Rights:**

CFA customers and/or regulatory agencies shall have the right to conduct surveys, perform surveillance audits and have access of supplier facilities to evaluate their capability to comply with contractual requirements.

2.9 **QSR9 – Approved Inspection Plan:**

When requested; suppliers shall submit a detailed inspection plan to CFA for approval before manufacturing begins for the part number ordered.

2.10 **QSR10 – Approved Source of Materials:**

All material used in fulfilling this order must be supplied by a supplier that is approved by CFA unless specifically authorized in writing to the contrary.

2.11 **QSR11 – Shelf Life Data:**

The supplier shall furnish the date of manufacturer, useable shelf life, expiration date of useable shelf life, any special storage conditions and any safety warnings for each item shipped.

The material safety data sheet must be included with each shipment.

Items will not be accepted by CFA where the remaining shelf life is less than 75% of the total shelf life.

2.12 **QSR12 – Identification and Control by Lot:**

The traceability of items shall be by lot number rather than individual serial number. The seller shall assign a common lot number to all items in a specific manufactured lot.

2.13 **QSR13 – Identification and Control by serial Number:**

If applicable, the seller shall identify individual serial numbers with all items shipped to CFA. The method of marking will be specified in the Purchase Order or on a furnished manufacturing drawing.

The seller shall maintain traceability of raw materials used in its manufacturing processes for each serialized item.

2.14 **QSR14 – Test and Inspection Reports:**

Test and inspection reports must accompany each shipment with measured data as required by the applicable procurement specification.

2.15 **QSR15 – Buyer Furnished Material:**

When CFA furnishes material, the Seller's System shall provide for the following:

2.15.1 Examination upon receipt for transit damage,

2.15.2 Verification of quantity and

2.15.3 Safe storage against damage, improper use or degradation.

The seller must provide a certification that informs CFA that the parts used were those furnished by CFA and that no un-authorized substitution was made.

2.16 **QSR16 – Approved Suppliers:**

All CFA approved suppliers are responsible for maintaining a list of their approved suppliers and shall have it available upon request for review by CFA. Information shall include the following:

2.16.1 Supplier name, address, contact information,

2.16.2 Nomenclature of parts or services provided, part numbers and

2.16.3 Other pertinent information requested by CFA.

The suppliers shall only purchase medical device related parts from suppliers which are controlled, approved and/or inspected by CFA.

2.17 **QSR17 – Changes to Work:**

The Supplier shall make no changes to work under a CFA Purchase Order or Contract. This includes any change in design, manufacturing process, materials, or otherwise which may affect form, fit, or function of the work without prior notification to and approval by CFA. Such notification shall consist of detailed drawings that clearly defining such changes and the date of such changes are proposed to be effective. Such notification shall not constitute approval of the proposed change nor relieve the Supplier of the obligation to comply with requirements contained in the Purchase Order or Contract. If the proposed change(s) are approved then the change approval shall be documented.

2.18 **QSR18 – Movement of Work:**

The Supplier agrees that the manufacturing and/or fabrication of work being delivered under this Purchase Order will not be moved to another production facility without the express written approval of CFA.

2.19 **QSR19 – Calibration System Compliance of Inspection, Measuring and Test Equipment:**

A system for the maintenance and calibration of inspection, measuring and test equipment shall be maintained. ANSI/NCSL Z540-1 applicable to calibration activities or an acceptable alternative: MIL-STD-45662A "Calibration System Requirements". All calibration standards must be traceable back to NIST (National Institute of Standards and Technology) and the NIST test number shall be included on the certificate of conformance. If any measuring equipment is found to be out of tolerance, "As Found, As Left" data shall be included.

2.20 **QSR20 – Foreign Object Debris (FOD):**

The supplier shall establish and maintain an effective FOD prevention program through a continual improvement approach that proactively addresses and controls the events (conditions and actions) leading to FOD.

2.21 **QSR21 – Export / Import Controls:**

The supplier shall control the disclosure of and access to technical data, information, and other.

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