Elbit Systems of America
Medical – KMC Systems, Inc.

EFFECTIVE 11/21/19

KMC Supplier Quality Requirements

Purpose

This document establishes general quality requirements for use on Purchase Orders from KMC Systems Inc. (hereinafter referred to as "KMC"). It is intended to clearly define requirements for the Supplier, to assure that all products delivered by the Supplier, on the Purchase Order (hereinafter referred to as "PO" conform to KMC's specified requirements (or those of KMC's Customer(s)) for quality, reliability and integrity. The Supplier shall flow down the requirements to its own sources.

If the Supplier has questions or concerns about the requirements, they are to contact KMC's Supply Chain Department, prior to accepting the job. All correspondence, including KMC responses, shall be in written format (preferably e-mail).

The Supplier's Quality Department is required to maintain this document on file for reference as necessary.

Scope

All documents, including drawings and specifications (regardless of origin, including KMC or its customer) are considered part of the PO requirements, when specified or referenced. Document revisions are effective as of the PO issue date, unless otherwise stated.

Providing exceptional value to the Supplier / Customer relationship must be the ultimate goal of both KMC and the Supplier. We as a team must work together to eliminate waste wherever it exists; and Suppliers who proactively engage in these processes will have the opportunity to receive ongoing business from KMC.

Communication is the key to collective cooperation, and must start in the advanced planning of product development. KMC will strive to involve suppliers at the earliest opportunity.

General Supplier Quality Requirements

1. Unless otherwise approved by KMC, the Supplier is required to have a Quality Management System in place, operated in accordance with, and accredited by, a third party certification body to the current version of the standard (such as ISO 9001:2015, ISO 13485:2016 or AS9100). Proof of accredited certification is to be furnished to KMC upon request.

2. KMC shall be immediately notified if the Supplier's Third Party certification is suspended or withdrawn.

3. Upon request, the Supplier shall provide all appropriate signed and dated product certifications (at the Supplier's sole cost and expense), within twenty four hours of request.

4. The Supplier will provide KMC, at a minimum, ninety days prior written notice before any change implementation, to afford KMC the means of determining approval for such changes that ultimately affect KMC's end customer. Examples of changes requiring notification include, but are not limited to:
    - Reduced inspection and/or testing
    - Changes in packaging, shipping or labeling of product
    - Product discontinuance
    - The use of alternate materials without KMC Quality written approval
    - Changes in Supplier or Manufacturer part number or name
    - Or changes similar to those listed in item 13

5. Source Inspection: Where the Supplier is notified that KMC wishes to carry out a Source Inspection activity, the Supplier shall notify the KMC purchasing representative at least five days prior to when items will be ready for inspection.

6. Suppliers performing final inspection should use the AQL Sampling Guide listed in below Item 12.

7. Suppliers will be issued a Supplier Corrective Action Request (SCAR) for non-conforming materials received; and responses are due back forty days from the date of issuance. SCAR's are evaluated by KMC for completeness and acceptability. Failure by a Supplier to respond to SCAR's on a timely basis will impact future sourcing decisions made by KMC.

8. Suppliers shall maintain records of manufacturing, inspection, testing and traceability, in the appropriate medium, for a period of not less than ten years.

9. Access to the Supplier's Facility: KMC, customer representatives, and regulatory authorities, reserve the right to access the supplier's facilities, and their lower-tier Suppliers, to assure that Supplier's product(s) comply with the requirements of this PO.

10. First Article Inspection (FAI) shall be conducted on the first delivery, and accomplished at the supplier's facility prior to initial shipment. The first piece produced, or a single piece sample is to be 100% inspected against the KMC drawings, including all drawing notes. A First Article Inspection Report (FAIR) shall be produced and submitted with the first shipment or via e-mail to KMC's Incoming Inspection department if the FAIR is not ready at the time of the shipment. The FAIR shall consist of the following:
    - Supplier Name recorded on the FAIR form.
    - Part number, part description, revision, and Purchase Order number
    - A copy of the drawing with each dimension / note with an identification number

- An inspection report clearly written in ink, or computer generated
- Cross outs shall be limited to a single line cross out, initialed and dated
- The inspection report shall include a listing of the print dimensions identified per the drawing
- The report shall be written using the same units of measure used on the drawing (i.e., inches or millimeters)
- The tolerance assigned to each dimension
- The actual inspection measurement, and the inspection equipment used
- A reject indicator for each dimension / note that is nonconforming
- The name of the author, or inspection stamp (clearly legible)
- The date the report was written

11. KMC Form #990-185 (SMRR, Supplier Material Review Request) is the vehicle by which a supplier requests material review action on non-conforming material in their possession. Suppliers are required to submit any quality deviations for review as soon as possible after identification, and all non-conforming material is to be retained by the Supplier until they have received disposition instructions from KMC.

12. Sampling inspections shall be made in accordance with ANSI/ASQ Z1.4 or equivalent, Accept/Reject Criteria shall be C= zero. AQL Sampling Guide:
    - Distributor (off-the-shelf) Items AQL 6.5% Level I
    - General Hardware Items AQL 6.5% Level I
    - Build-To-Print Items AQL 1.0% Level II
    - Items on rolls or reels 1 piece Special

13. Suppliers shall submit FAIR's (New/Delta) for the following changes:
    - Facilities: Include a change to the manufacturing or machining method/process, machining equipment, machine set-up, test and inspection equipment, processing tanks or equipment, manufacturing location (total site relocation) or machines re-sitting.
    - Procedures: A procedure change to, or of the manufacturing methods, procedures, planning and/or sequencing used in or applicable to the manufacturing, processing, assembly, inspection and/or testing of an items for KMC.
    - Personnel: A large turnover of staff, (i.e. where new or a different group of people producing the item); manufacturing, processing, assembling, inspecting, and/or testing the item (this essentially results in a loss, displacement or replacement of previous learning, capability, skills).
    - Configuration: Modification/revision status of drawings and or drawings referenced specifications and test methods, general drawing notes.

14. Suppliers are permitted to use sub-suppliers (also known as sub-tier suppliers) for non-machining and non-assembly activities such as painting, plating, coatings, marking, heat-treating, passivation and cleaning. Notification of these sub-suppliers to KMC Medical is not necessary. Suppliers are responsible for ensuring the quality of the sub-suppliers. Certificates and traceability information from the sub-supplier services shall be maintained.

    For activities that involve machining, welding, soldering, brazing, molding and/or physical sub-assembly work, the supplier must notify KMC Medical in writing regarding the sub-supplier company name and address, what the sub-supplier scope of activities will be and how the supplier will be monitoring the sub-supplier activities. If there is a major change to an existing sub-supplier's status (i.e. natural disaster damage, corporate take-over, etc.) or if an additional sub-supplier is approved for the same activity, KMC Medical shall be notified in writing. Suppliers are responsible for ensuring the quality of the sub-suppliers. Certificates and traceability information from the sub-supplier services shall be maintained.

    If any sub-suppliers are required to adhere to special requirements (RoHS compliance, Counterfeit prevention, Conflict Minerals, ESD compliant packaging, etc.) the supplier is responsible for ensuring the sub-supplier is adhering to and certifying to these requirements.

Supplier:

Date: _____

Company Name: _____

Quality Representative Name: _____

Title: _____

KMC:

Name: _____ Date: _____

Title: _____