

Supplier Quality Requirements for Purchased Materials or Service

1.0 Scope

This Supplier Quality Requirements Document defines the terms and conditions relating to the quality of materials or services supplied to PM, which are used in or for the production of PM products.

2.0 General Requirements

2.01 Unless otherwise specified and approved by PM, the Supplier is required to have an implemented and maintained Quality Management System (QMS) certified by a third-party body to the current version of a standard such as ISO 9001.

2.02 Unless otherwise specified and where applicable, the Supplier shall comply with the latest revisions of applicable standards, including but not limited to JEDEC and IPC.

2.03 Upon request, the Supplier shall provide all relevant product certifications, including all applicable safety, regulatory, and operating system certifications, at the Supplier's sole cost and expense.

2.04 Evidence of QMS certification and successful surveillance audits shall be provided to PM upon request.

2.05 PM is committed to achieving ISO 14001 certification for its environmental management systems across all manufacturing operations. The goal is to deliver products that are environmentally responsible throughout their lifecycle. The Supplier shall operate in an environmentally responsible manner.

2.06 The Supplier shall have a disaster recovery and business continuity plan that minimizes risk to PM in the event of natural disasters, labor disputes, or other supply chain disruptions. Evidence of such plans shall be available upon request.

2.07 Materials shall comply with PM specifications or, if unspecified, with Supplier's specifications effective at the time of receipt of PM purchase order.

2.07.1 The Supplier/Manufacturer must provide prior notice of any changes to materials or processes. Written preliminary approval from PM is mandatory.

2.08 The manufacturing date code of supplied materials shall not exceed 24 months at the time of receipt by PM unless otherwise agreed in writing prior to the release of the purchase order. Some commodities may have shorter shelf-life requirements per industry standards. A minimum of 6 months must remain on the material shelf life before expiration. Customer-specific shelf-life requirements will be communicated with the PO release.

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2.09 The Supplier shall maintain a First-In-First-Out (FIFO) inventory system to ensure that non-conforming or outdated products are not inadvertently shipped to PM.

2.10 Supplier Certification:

- **2.10.01** Supplier acknowledges that certification may require an audit by PM to assess Supplier's capability to provide Material(s) or Service(s). These audits may be remote or on-site. PM reserves the right to require an on-site audit prior to certification.
- **2.10.02** Certification status is subject to Supplier performance and may be changed by PM at any time.

2.11 Changes to the Supplier's QMS or significant organizational changes must be communicated to PM immediately.

3.0 Shipping, Packaging, and Labeling Requirements

3.01 Certificate of Conformance (C.O.C) and Certificate of Test (C.O.T) for custom shipments must include: Manufacturer Name, Manufacturer Catalog Number, and signature of a certified vendor representative.

3.02 All Electrostatic sensitive devices (ESD) shall be properly packaged to provide protection from electrostatic discharge.

3.03 Packaging shall not negatively affect material quality or introduce contaminants.

3.04 Moisture Sensitive Devices:

- **3.04.01** All products shall be packaged in ESD Moisture Barrier Bags (MBB).
- **3.04.02** Each MBB shall be labeled per PM requirements.
- **3.04.03** All moisture sensitive devices shall comply with J-STD-033 and J-STD-020 at their latest revisions.

3.05 Products shall be labeled (human-readable and barcode - Code 39) at the lowest packaging level (e.g., reel, tube, tray). Labels must include Supplier Name, Supplier Part Number, Manufacturer Name, Manufacturer Part Number, Product Description, Manufacturing Date, Lot Code, and PM Purchase Order Number.

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4.0 Product Quality Notification

4.01 If the Supplier suspects that non-conforming product was shipped, they must notify PM Supplier Manager and the buyer who placed the order immediately in writing.

4.02 If the Supplier identifies non-conforming product prior to shipment and seeks a deviation or concession, a written request must be sent to the buyer. Final disposition will be determined by PM.

5.0 Expectations When Failures Occur – Failure Analysis and Corrective Action

5.01 The Supplier shall maintain a documented corrective action procedure to respond to PM complaints. To assure timely resolution of non-conformance issues, Supplier shall apply appropriate problem-solving techniques to identify root causes and implement permanent corrections.

5.02 When a non-conformance is identified, PM will issue a Supplier Corrective Action Request (SCAR). A detailed and documented root cause and corrective action plan is required.

6.0 Quality Record Keeping

6.01 The Supplier shall retain quality records by applicable medical or general standards, or as agreed upon with PM, and in no case for less than 3 years.

6.02 Quality records shall be kept and maintained to provide evidence of Product conformance to Supplier's quality management system.

6.03 For Suppliers providing Material used on medical Products, records shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 3 years from the date of release for commercial distribution by the manufacturer.

7.0 RoHS / WEEE Compliance

7.01 The Supplier shall comply with PM's RoHS and WEEE specifications and requirements.

8.0 Requirements for Aerospace / Defense Suppliers

8.01 The Supplier shall be aware to the contribution and the importance of product/service conformity, product safety, and ethical behavior.

8.02 If key characteristics, critical items, or special requirements are defined, the Supplier shall perform work per customer requirements.

8.03 The Supplier shall ensure that there is no FOD (Foreign Object Damage) in any item covered by this Purchase Order, in the manufacturing process or in any of the packaging stages

8.04 Suppliers providing products and sub-assemblies for assemblies where Rafael is the final customer are required to comply with document Raf#3263503 (93.00.63) in its latest revision.

9.0 Prevention of Counterfeit Component Use

9.01 The Supplier must avoid purchasing counterfeit components. Authorized distributors must comply with AS5553, AS6832, and AS6174 standards.

9.02 The Supplier must be an OEM or authorized distributor of the supplied item.

9.03 The Supplier must maintain a method that will ensure traceability of the supply chain of the items / components supplied from the manufacturer.

9.04 If the Supplier isn't authorized distributor, the Supplier must attach to the shipment all documents proving the purchase order traceability. The traceability will include: details of those involved in the supply chain, from the OEM to the direct source from which the item was purchased.

9.05 If the Supplier is not an OEM or authorized distributor, they must attach an original Certificate of Conformance (COC) issued by the OEM with each shipment.

10.0 Requirements for Mechanical and Special Process Subcontractors

10.01 The Sub-contractor undertakes to carry out the work for P.M. in accordance with the drawings / specifications / documents it will receive from P.M. together with a purchase order.

10.02 Raw materials must be purchased from customer-approved suppliers. They must be from a single batch and include a COC/COT from the original manufacturer.

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10.03 Special processes (coating, painting, heat treatment, etc) should only be carried out by subcontractors approved by final customer.

10.04 It is the subcontractor's responsibility to ensure that their special process sub-contractors are approved by the final customer.

10.05 Special process subcontractors must periodically validate their processes and provide documentation to PM upon request.

10.06 Test samples (coupons) shall be included when required in the purchase order.

10.07 Inspection shall be conducted according to Squeglie or comparable sampling plan, C=0, AQL 2.5%, unless otherwise specified.