



## Knightsbridge Plastics, Inc.

3075 Osgood Court, Fremont, CA 94539  
Tel: (510) 440-8444 • Fax: (510) 440-8464  
[www.kpi.net](http://www.kpi.net)

**ISO 9001:2015 Certified**  
**ISO 13485:2016 Certified**

## **SUPPLIER QUALITY REQUIREMENTS**

### **1) General**

The following quality requirements apply to all purchases that have the potential to impact the quality of the product and/or services provided by Knightsbridge Plastics, Inc. (KPI) or KPI quality management system.

Suppliers shall keep confidential all non-public information received from or created by KPI under this document. Supplier shall disclose to KPI in a timely manner any compromises in the Supplier's security that could impact KPI product, data, or product related software.

### **2) Specifications**

Supplier will, as applicable, provide products or perform services in compliance with the requirements specified by KPI's, including but not limited to, requirements in the following KPI documents:

- purchase orders,
- product prints,
- material specifications,
- and drawings or other engineering documentation

Supplier will communicate to KPI if there are any questions or issues regarding the interpretation of any of the specifications provided by KPI.

### **3) Quality Management System**

Supplier will maintain a Quality Management System that complies with the requirements set forth in ISO 9001 or ISO 13485. In lieu of ISO certification, KPI may (to the extent necessary to meet KPI's business needs) monitor supplier performance, schedule an on-site audit, and/or perform supplier evaluation for adequate business management systems which correspond toward current ISO 9001 and ISO 13485 Quality Management Systems.

The Supplier shall notify KPI, via email or written correspondence, of any significant changes in Supplier's Quality Management System or processes that may affect quality of products/services. When the change is not foreseeable, Supplier shall notify KPI of the change no later than two days from the change. These changes include, but are not limited to, changes in management with executive responsibility or changes in management responsible for quality.

Supplier will notify KPI, via email or written correspondence, within 15 business days of any changes to the status of their Quality Management System registration or certification.

### **4) Product Complaints and Recalls**

KPI will promptly notify Supplier of any nonconformities or adverse reports that implicate Supplier's processes (i.e., manufacturing, packaging, or distribution).

If Supplier becomes aware of any nonconformities that impact the products or services the Supplier provides to KPI, it is the responsibility of the Supplier to notify KPI, **via email or written correspondence**, no later than two business days from the discovery of the nonconformity.

In the event KPI is required or voluntarily decides to recall or withdraw a product provided by Supplier, Supplier will fully cooperate with KPI in connection with such recall or withdrawal.



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### 5) Process Control

Supplier will ensure that all processes that directly affect the quality of products provided, or services performed are clearly defined and carried out under controlled conditions. Supplier's process control should include:

- use of suitable equipment and environment to produce products.
- documentation of changes regarding production and process controls.
- sufficiently trained, qualified, and competent personnel to perform services or operations on KPI's products.
- defined criteria for workmanship standards, such as representative samples or illustrations.
- identification and traceability of raw materials, components, and products during all stages of receipt, processing, testing, storage, shipment, and distribution.
- such other process controls as KPI may require from time to time.

### 6) Equipment Control, Maintenance and Calibration

Supplier shall have documented systems in place to ensure process and test equipment is controlled, maintained, and calibrated at stated frequencies, to ensure it is suitable for its intended purpose and is capable of producing valid results.

### 7) Changes to Supplier Processes or Materials

Supplier shall notify KPI, **via email or written correspondence**, of any significant process changes that could affect KPI's Quality Management System prior to implementation of the proposed change. Supplier will document proposed change requests in reference to this Section 6 and will send the proposed change request, **via email or written correspondence**, to KPI. Supplier must obtain written or email approval from KPI before changes to product or service is made effective at Supplier's location. Significant process or material changes include, but are not limited to, changes to the production processes, manufacturing materials, manufacturing location, outsourced products, services, or equipment associated with KPI's products or services.

If Supplier subcontracts to third parties for products or services, Supplier will ensure that these subcontractors are monitored to the extent necessary to ensure no adverse impact on products or services.

Supplier, to the extent necessary, will ensure that all incoming products, including raw material, whether from an external party or from KPI's facility, conform to Supplier's needs to provide KPI conforming product/services. Supplier will maintain processes to control segregation of product throughout production.

### 8) Corrective and Preventive Action with regards to Non-Conforming Product

Supplier shall establish and maintain procedures/processes for control of non-conforming products. This includes identification of non-conformances, segregation, or quarantine (as appropriate), investigation of cause and evaluation, and disposition of non-conformances.

Supplier shall, at the request of KPI, perform investigations and take actions on any KPI Corrective and Preventative Actions ("CAPAs"). Supplier agrees to respond to CAPAs within the date specified on the SCAR/CAPA form and/or any other documentation as requested.



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### **9) Certification and Shipment**

Supplier will utilize appropriate packaging for shipments to prevent damage during transit. When appropriate, Supplier will also provide a statement of conformance to all product prints, material specifications, quality work instructions, and specifications each in accordance with any revisions of documents provided by KPI.

Supplier shall have systems in place to control shipment of products so that only products approved for release are shipped. Supplier shall ensure that no obsolete, rejected, expired, or deteriorated products are shipped.

### **10) Restricted Substances/Material Declaration**

Products and services supplied to KPI are expected to meet all applicable requirements of country, federal, state, and local environmental regulations. Supplier acknowledges that KPI has certain legal, regulatory, environmental, and contractual reporting obligations and Suppliers of packaging, components and product agree to provide KPI with information about the specific composition (e.g., trade or chemical name, color, grade, etc.), including quantity of all constituents used in the products and packaging and/or provide specific certifications to KPI upon request. Supplier also agrees that latex gloves shall not be used at any point.

### **11) Records**

Supplier will maintain records for products or services provided to KPI for a minimum of 10 years. KPI will have timely access to all manufacturing and quality records pertaining to KPI's products/services. Supplier will use reasonable efforts to maintain and store documents in a manner to prevent loss or deterioration.

### **12) Audits**

Supplier will allow KPI, and any third parties designated by KPI, to perform audits of its facilities, including but not limited to "notified body" unannounced audits, national and international authorities audits. If corrective actions are needed, Supplier agrees to provide CAPA plans as required hereunder.