

# SUPPLIER QUALITY REQUIREMENTS

---



**Quality Requirements:** Supplier shall maintain an ISO, AS or Military Standard equivalent quality system acceptable to Buyer. Supplier shall ensure its quality system is compliant with a currently maintained and published consensus industry standard quality system specification as appropriate to the Supplier's activities.

**Process:** Suppliers must have delegated process and inspection authority to ensure all applicable process and material specifications are met and documented accordingly. Suppliers are further required, upon request, to demonstrate and provide evidence of your processes to planned results and establish arrangements for the processes including:

- Define criteria for review and approval of the process(es)
- Determine conditions to maintain approval
- Approval of facilities and equipment
- Qualification of personnel
- Use of specific methods and procedures for implementation and monitoring process(es)
- Requirement for record retention

**Contribution:** It is imperative that supplier and the supplier's personnel are aware of your contribution to the conformity of the product and service you provide; the contribution to product safety and the importance of ethical behavior as it ultimately affects the conformity of the product(s) we provide to our customers and all of our continued business.

**Records:** Supplier shall maintain complete records of all manufacturing, process capability (if applicable), and tooling controlled, and inspection and test, including copy of CoC, unless

# DIAGNOSTIC SOLUTIONS INTERNATIONAL, LLC SUPPLIER QUALITY REQUIREMENTS

---



otherwise stated in this PO. Upon Buyer's request, Supplier shall make records available to Buyer for at least (7) years after completion of this PO and for longer periods as may be specified elsewhere in the PO. Upon Buyer's request, Supplier shall provide records of inspection tests of processed Items and process control tests to Buyer. Upon Buyer's request, Supplier shall forward specific records to Buyer at no additional cost, price, or fee to Buyer.

**Calibration:** Supplier shall maintain a documented calibration system for the calibration and maintenance of tools, inspection and test equipment. Supplier shall have and maintain a calibration system that is compliant to prevailing industry requirements in accordance with ISO 17025, ISO10012-1, or ANSI Z540.

**Right of Entry:** Diagnostic Solutions International, LLC Customers, Government regulatory agencies and Diagnostic Solutions International, LLC shall have the right of entry into supplier's facility for the purpose of verification of materials, quality systems, manufacturing and documentation.

**Counterfeit Material / Parts:** It is the responsibility of the supplier to deliver parts, Material and or hardware that is not counterfeit. The supplier shall verify that the delivered hardware does not contain any counterfeit materials. Verification SHALL include procurement documentation that the supplier purchased the product directly from the original equipment manufacture or from a franchised distributor, resale or aftermarket supplier who is authorized by the original manufacturer. The supplier SHALL also perform an evaluation that could include: visual inspection of the device, markings, evaluation, shall also be made to a known authentic sample or with assistance from the original manufacture.

**Raw Material Traceability:** All items manufactured under Diagnostic Solutions International, LLC Purchase Order shall be traceable to raw materials used. Traceability and inspection records shall be available upon request by Diagnostic Solutions International, LLC or customer representatives. Identification of raw materials used, shall include, as applicable, but not limited to, the following types of information - lot number, material type, specification, heat number, etc.

# DIAGNOSTIC SOLUTIONS INTERNATIONAL, LLC SUPPLIER QUALITY REQUIREMENTS

---



In any case, supplier shall record sufficient identification information to adequately identify all material in such a manner that full traceability of raw materials used is included.

**Nonconforming Product:** Notification must be made regarding any nonconforming product; to obtain approval for nonconforming product disposition, notification of changes in product disposition, notification of changes in product and/or process, change of suppliers, changes of manufacturing facility location and where applicable, obtain approval and flow down to the supply chain the applicable requirements including customer requirements.

**Material Review Board (MRB) Authority (If Stated on PO):** The supplier shall notify Diagnostic Solutions International, LLC Quality Assurance of any "use as is" or "repair" non-conformances to the requirements of this order "use as is" and "repair" dispositions shall be submitted to DSI prior to implementation. Suggested dispositions, identification of the cause of non-conformance, and the corrective actions taken shall be submitted in writing. Further work shall not be performed until directed by Diagnostic Solutions International, LLC in writing.

**Certification of Compliance:** Certification documents are required from supplier and sub-tier supplier, and shall be identified with, and include, the following:

1. The DSI purchase order number and item number.
2. Quantity, Lot, and/or Serial Numbers.
3. Date of Manufacture (D.O.M.).
4. Part Number and Revision as specified on purchase order.
5. Signature, Title, and Date by an authorized representative of the issuing organization

**Configuration Management:** Supplier shall notify the buyer immediately of any changes to the characteristics or configuration of the product and/or processes used to manufacture the product. When required, supplier shall obtain written approval of changes from DSI.

# DIAGNOSTIC SOLUTIONS INTERNATIONAL, LLC SUPPLIER QUALITY REQUIREMENTS

---



**Packaging / Handling:** Product intended for delivery to DSI shall be handled and packaged in manner as necessary to prevent damage during handling and transit.

## *Hazardous Materials*

Hazardous materials, as defined by the EPA, shall be packaged and clearly identified in such manner as to include any and all special handling, packaging, storage, environmental, or other requirements imposed by statute or regulation.

**Limited Shelf Life Material:** The supplier shall identify each item, package, or container of limited-calendar-life material with the cure or manufacture date, storage temperature, special handling conditions and requirements, in addition to the normal identification requirement of name, part number, specification number, type, size, quantity and manufacturing recommended shelf life. This identification, including special handling conditions and requirements, shall be recorded on certifications and shipping documents for the material.

**First Article Inspection (If Stated on PO):** A First Article Inspection Report shall be required when the first production units are manufactured. The report shall include all drawing characteristics and notes, required tolerance range, actual measurement results, and where physical testing is required, the results of the test(s).

**Source Inspection (If Stated on PO):** Diagnostic Solutions International, LLC will inspect the material submitted on this purchase order at the supplier's facility. Source inspection approval or acceptance by the Quality representative shall not constitute final approval or acceptance by Diagnostic Solutions International, LLC of the items covered by the purchase order, nor shall it relieve the seller of their responsibility to furnish acceptable product.

**Test Reports (If Stated on PO):** Each shipment must be accompanied by one (1) legible and reproducible copy of actual test results identifiable with test parameters and product submitted. These reports must contain the Test/Inspection Stamp of the individual performing the task, or the signature and title of the authorized representative of the agency performing the test.

# DIAGNOSTIC SOLUTIONS INTERNATIONAL, LLC SUPPLIER QUALITY REQUIREMENTS

---



**Raw Material Certification (If Stated on PO):** Each shipment must be accompanied by one (1) legible and reproducible copy of the Raw Material Certification. The Certification shall be from the Mill source and lists the actual test values.

**Special Process Certification (If Stated on PO):** A certificate shall be issued with each shipment and must state that special processes demonstrate compliance with the drawing requirements, specifications or purchase order, and is performed by a Diagnostic Solutions International, LLC, Design Authority, and/or government approved source. The certificate shall contain the signature of an authorized representative of the supplier.

**Responsible Supply Chain Management:** All Suppliers must comply to the Modern Slavery Act. These standards include expectations that suppliers shall not use child labor or forced labor, and that they shall comply with their countries legal minimum wage requirements, prevent discrimination or harassment in the workplace, and provide fair working conditions. All suppliers are asked to certify that products and their component parts that are provided to DSI comply with the laws regarding slavery and human trafficking of the country or countries in which they do business.