



## PO Quality Clauses / Terms and Conditions

The following requirements apply at minimum, additional requirements may be incorporated with the company purchase order.

Material and Hardware Providers: Q1, Q2, Q3, Q4, Q5, Q7, Q8, Q16, Q19A, Q19B, Q21, Q22, Q23

Special Process Providers and their Sub-Tiers: Q1, Q2, Q3, Q7, Q8, Q10, Q11, Q16, Q18, Q19B, Q21, Q23

Fabrication Providers and their Sub-Tiers: Q1, Q2, Q3, Q5, Q6, Q7, Q8, Q9, Q10, Q11, Q12, Q13, Q15, Q18, Q19A, Q19B, Q21, Q22, Q23

### **Q1 QUALITY SYSTEM REQUIREMENTS**

The Seller shall provide and maintain a system that complies with ISO9001, AS9100 or other QMS appropriate to the product and approved by China Surgical Tools.

### **Q2 MRB AUTHORITY**

Material Review Board Authority is not authorized on this Purchase Order.

### **Q3 CHANGES**

The Seller shall notify the buyer of any proposed changes in design, fabrication methods, or processes previously approved by the Buyer and/or Buyer's Customer. Changes articles shall be clearly identified in a different manner from previous articles. When a proprietary item is procured by the Buyer, the Seller shall notify the Buyer of any changes. The seller shall not incorporate any change, deviation, or waiver which affects the customers' specifications or drawings prior to receipt of written authorization from the Buyer.

### **Q4 RAW MATERIALS**

Raw materials shall be accompanied with certifications, chemical and/or physical test results. Certification shall contain the following minimum requirements: material type, alloy specification, size/shape, heat lot number, chemical composition and measured mechanical properties. The Seller shall also certify to the specific requirements defined on the print specifications and/or the face of the purchase order.

### **Q5 RAW MATERIALS USED IN PURCHASED ARTICLES**

Results of tests performed on specimens or detailed analyses of Seller's acceptance results on all raw materials that are required to satisfy specification requirements and which are employed in the fabrication of the articles purchased on a subcontract or purchase agreement shall be made available to the Buyer upon request.

### **Q6 AGE CONTROL AND LIMITED LIFE PRODUCTS**

Seller records for age control/life limited products shall reflect useful life and when useful life is expended.

### **Q7 IDENTIFICATION AND DATA RETRIEVAL**

Where and to the extent traceability is a specified requirement the Seller shall apply a unique identification/lot numbers to identify batches of parts or unique serial numbers to each part, as specified on the purchase order. Lot and serial numbers must provide traceability to all related quality records including: raw stock test certificates, special process certificates of conformance, work order and inspection data (see Q8 Seller Records).

### **Q8 SELLER RECORDS**

The Seller shall maintain suitable inspection and test records to serve as evidence of conformance with specified requirements. Such records shall be legible and traceable to the product involved. These records shall be maintained for a minimum of seven (7) years after final payment or as specified elsewhere in the purchase order. See requirement(s) stated elsewhere in this order, for specific records to be forwarded to the Buyer.



## PO Quality Clauses / Terms and Conditions

### **Q9 INSPECTION AND TEST CHARACTERISTICS**

Seller shall inspect and/or test as applicable, all characteristics defined by the purchase order, applicable drawing specifications, pertinent to the work that the Seller is responsible for performing. Machining, welding and precision cutting/grinding suppliers will provide Inspection Measurement Data per ANSI/ASQ Z. 1.4-2008, General Inspection Level 1. Raw Materials used shall require certification as stated in Q4 with each lot shipped. Any special processes contracted by the Seller will require a Certificate of Conformance as stated in Q7 to be submitted with each lot shipment.

### **Q10 RESUBMISSION OF NONCONFORMING ARTICLES OR MATERIALS**

Non-conforming articles and materials returned by the Buyer and subsequently re-submitted by the Seller shall bear adequate identification of such non-conformance, either on the articles, materials or applicable Seller records. The Seller shall provide evidence that the cause for the non-conformance(s) have been corrected and actions taken to preclude any recurrence. Seller shall communicate immediately with Buyer to notify them of any non-conformance and identify corrective action to be taken, whether or not the item is returned to Buyer.

### **Q11 BUYER QUALITY ASSURANCE ACTIVITY AT SOURCE**

The buyer and its customers reserve the right to perform inspections and tests on all articles, materials or services at all time and places. The Buyer and its customers also reserve the "right of entry" which shall allow the Supplier, Customer or Regulatory agency to determine and verify the quality of work, records, and materials at any place, including the plant of the subcontractor.

### **Q12 GOVERNMENT SOURCE INSPECTION**

When the Government or Customer elects to perform inspection at the Seller's facility, the following requirement applies: All work on this order is subject to inspection and test by the Government or Customer at any time or place. The Government or Customer quality representative who has been delegated quality assurance functions on this procurement shall be notified immediately upon receipt of this order. The Government or Customer shall also be notified forty-eight (48) hours in advance of the time articles or materials are ready for inspection or test.

### **Q13 PROCUREMENTS OTHER THAN THOSE REQUIRING GSI**

For procurements which do not require Government Source Inspection, the following requirement applies: The Government has the right to inspect any or all work included in this order at the Seller's plant.

### **Q14 ITAR FLOW DOWN**

If the order falls under the regulations of ITAR (International Traffic and Arms Regulations), all manufacturers, exporters, brokers of defense articles, defense services or related tech data are required to register with the DDTC (Director of Defense Trade Controls). All license requirements imposed by ITAR are the sole responsibility of the subcontractor in possession of the purchase order.

### **Q15 CALIBRATION SYSTEM**

The supplier and supplier subcontractors shall meet and maintain a Calibration System in compliance with Calibration System Requirements of ISO17025 or ANSI Z540-1.

### **Q16 SELLER'S FLOW DOWN OF REQUIREMENTS**

Supplier shall flow down requirements and/or key characteristics in the purchase documents to sub-tier suppliers as applicable.



## PO Quality Clauses / Terms and Conditions

### **Q17 STATEMENT OF CONFORMANCE**

Each shipment must be accompanied by at least one legible copy of a statement of conformance. This statement shall specify that all contractual requirements have been adhered to including all specifications and other applicable documents as cited in the purchase agreement and that evidence is on file for review by a quality representative. The statement of conformance shall provide a link (via the Supplier's internal job number, work order number, or other identifier) to all documentation for this product. The statement of conformance must contain at minimum: the part number, purchase order number, quantity, revision as specified on the purchase order, name and address of the company certifying the part.

### **Q18 CLEANING AND PACKAGING**

Unless otherwise stated on the Purchase Order, Flow Down Specification(s), Drawing(s), and/or Quality Notes, cleaning and packaging shall be based on "best commercial practices". The seller will assure that an adequate packaging procedure/process is in place to protect parts or assemblies during transportation i.e. UPS, Fedex, etc.

### **Q19A DFARS 252.225-7008/7009**

When specified on the Purchase Order, the Supplier certifies that all products supplied against the Purchase Order fully comply with DFARS Clause 252.225-7008/7009, Preference of Domestic Specialty Metals including Alternate Clause 1.

### **Q19B DFARS 252.204-7012**

When specified on the Purchase Order, the Supplier shall comply with DFARS Clause 252.204-7012, in accordance to NIST SP800-171 and procedures for cyber security based on industry standards (e.g. ISO 27000, NIST 800-53).

### **Q20 DEFENSE PRIORITIES AND ALLOCATIONS SYSTEM (DPAS)**

The DPAS provides that the DoD contracts are assigned priority ratings to assure that these contracts are afforded production priorities for delivery ahead of unrated orders which includes commercial orders. Ratings are assigned to DoD contracts and enforced in both peacetime and war or emergencies. The contractor is obligated to accept the rated order, to schedule production operations to satisfy delivery requirements of each rated order, and to extend the priority rating to suppliers to assure that the item is delivered in the timeframe requested.

### **Q21 RIGHT OF ENTRY**

The Company, their representatives, customer(s) and any regulatory agencies shall have "Right of Entry" to the Supplier facility and at any level of the supply chain, as well as quality records for the purpose of the audit, surveillance and/or verification of quality of work, documentation or material. The Supplier shall ensure that this requirement is flowed down to their supply chain.

### **Q22 COUNTERFIT PARTS & MATERIAL**

Supplier shall have a counterfeit parts avoidance, detection, mitigation, and disposition program. Seller shall only deliver authentic components, devices, pieces, material, modules, assemblies, subassemblies, goods, etc. that are manufactured by or obtained from original equipment manufacturers (OEMs), original component manufacturers (OCMs), or authorized distributors. Seller shall make available POC documentation that authenticates and provides traceability of the Parts to the applicable OEM or OCM.

### **Q23 AWARENESS**

Supplier shall ensure their employees are aware of the following: 1. Their contribution to our product conformity; 2. Their contribution to our product safety; 3. The importance of ethical behavior.