P & Q Clauses

P04 (P04) PO Clause - SDS Sheet

(P04) Please send a "Safety Data Sheet" that meets the OSHA hazard communication standard on all potentially hazardous chemicals or materials with your shipment. Mark to the attention of "Purchasing".

P17 (P17) PO Clause - Insurance Clause

(P17) INSURANCE CLAUSE: Contractor is to maintain all necessary liability insurance to protect themselves against claims for bodily injury or death of any person or persons whether or not employed by contractor, which may arise from any operation in connection with work covered by this order. Required insurance in all cases will be workers' compensation and employers' liability for the state involved and public liability insurance. If you select any portion of this order, it will be necessary that you carry contractor's protective liability insurance. A copy of your "Certificate of Liability Insurance" must be forwarded to Lisi Medical Remmele prior to beginning work on this order. You must provide a safe work environment. Contractor will abide by Lisi Medical Remmele's safety policy of wearing safety glasses with side shields at all times in designated areas.

Q00 (Q00) QA Clause - No Certs Required

(Q00) No Certifications of any type required.

Q01 (Q01) QA Clause - Cert. of Conform.

(Q01) You are required to submit with each shipment a Certificate of Conformance (C of C) signed or stamped by an authorized Quality Representative or designate, which references Lisi Medical Remmele's Purchase Order Number (purchase order#) and Serial Number (S/N)/ lot number if applicable and states that the materials furnished to Lisi Medical Remmele are in conformance with the specific data listed on the purchase order, drawings, and all applicable requirements and standards to prescribed revision levels, and that supporting documentation is on file including approved written procedures for all special processes to reference specifications. Lisi Medical Remmele, its Customers, and Regulatory Agencies reserve the right of access to supplier's facilities and all applicable quality records pertaining to this purchase order. Quality records must be maintained by the supplier for a minimum of seven (7) years, or as specified by the Lisi Medical Remmele Purchase Order.

Q02 (Q02) QA Clause - Test Certs

(Q02) One copy of the actual test reports referencing Lisi Medical Remmele's purchase order, supplier name and address, and/or independent laboratories name and address, part number(s), part name, serial number if applicable, lot/batch, list of parameters tested, and test date, must accompany each shipment. These reports shall be validated by an authorized quality representative of your company by signature or inspection stamp. Lisi Medical Remmele, its Customers and Regulatory Agencies reserve the right of access to supplier's facilities and all applicable quality records pertaining to this purchase order.

Q03 (Q03) QA Clause - Material Certs

(Q03) One copy of the actual chemical composition and actual mechanical properties for each lot, batch, or heat, shall accompany each shipment and must reference Lisi Medical Remmele's Purchase Order #. Applicable ASTM test methods must also be referenced. Either Lisi Medical Remmele's Purchase Order # shall be referenced on the cert, or a packing list referencing the Lisi Medical Remmele Purchase Order # and mill cert. Heat Lot # shall accompany the cert. Lisi Medical Remmele, its Customers and Regulatory Agencies reserve the right of access to supplier's facilities and all applicable quality records pertaining to this purchase order.

Q08 (Q08) QA Clause - Process Approval

(Q08) Your process(s) must be approved by our customer before performing any specialized processing to this purchase order. You are required to notify Lisi Medical Remmele Quality Assurance of any changes which may negate any previous qualifications, certifications, and approval status, as related to this order.

Q10 (Q10) QA Clause - Control Changes

(Q10) The supplier is responsible for controlling changes to articles manufactured or processed to drawings or specifications. The supplier shall notify Lisi Medical Remmele of any proposed changes to approved designs, processes, fabrication methods, or nonconforming material, and to obtain Lisi Medical Remmele's approval prior to change incorporation and material delivery.

Q11 (Q11) QA Clause - Critical Parts

(Q11) Articles covered by this order have been identified as critical. You are required to assure that affected employees are aware of the critical nature of these articles and that appropriate steps are taken to safe-guard product quality.

Q12 (Q12) QA Clause - Packaging

(Q12) Supplier shall provide all necessary care in packaging to insure Lisi Medical Remmele parts or materials are not damaged. Stacking of plates, bars, sheets, coils, castings, or parts, shall not cause warping, distortion, nicks, dents, gouges, scratches or other damage. Inadequate use of pallets, cardboard, bags, boxes, containers, bubble wrap, Styrofoam chips, foam, paper media, etc., meant to protect parts or material delivered to Lisi Medical Remmele or to another destination on Lisi Medical Remmele's behalf, shall not be the cause of material or part damage, or contamination.

Q22 (Q22) QA Clause - ISO Requirement

(Q22) Supplier is responsible for maintaining a documented quality system patterned after or in compliance with ISO 13485, or 9001, or 17025, as applicable to the work scope stated in this order. Procedures, plans, and records will be made available for review by request of authorized Lisi Medical Remmele Supply Chain representatives.

Q23 (Q23) QA Clause - Calibration

(Q23) This/these instrument(s) must be calibrated using standards traceable to NIST per the guidelines specified in ANSI/NCSL Z540.3 and ISO/IEC 17025. Only those line items with (Q23) are to be calibrated to this standard. Other specifications/standards may also impose specific calibration requirements.

Q24 (Q24) QA Clause – Drawing /Specs

(Q24) A drawing/specification package must accompany parts when shipped to the supplier. This same drawing/specification package must be returned by the supplier with the parts. Note: These documents are controlled. Copying or otherwise altering these documents is prohibited unless prior authorization has been given by Lisi Medical Remmele.

Q29 (Q29) QA Clause-Nonconforming Parts

(Q29) Supplier must establish controls to assure that nonconforming materials are identified, segregated, dispositioned, and controlled to prevent inadvertent use. Supplier must document and notify Lisi Medical Remmele of any nonconforming product identified in manufacture. Contact responsible Buyer for further instructions.

Q32 (Q32) QA Clause - 100% Inspection

(Q32) Supplier is required to perform 100% Inspection on all parts supplied on this purchase order. Actual readings for all dimensions must be recorded and submitted with the associated parts on this order. In addition, inspection records must be retained for a minimum of seven (7) years, or as specified by the Lisi Medical Remmele Purchase Order.

Q35 (Q35) QA Clause - Sampling Plan Req

(Q35) INSPECTION SAMPLING PLAN - Sampling procedures employed by the supplier must be in compliance with ANSI/ASQZ1.9 (current revision), and ANSI /ASQ Z1.4 (current revision).

Q40 (Q40) Mat'l Cert Stored at Supplier

(Q40) One copy of the actual chemical composition and actual mechanical properties for each lot, batch, or heat, shall be maintained at the Supplier for each shipment and must reference Lisi Medical Remmele's Purchase Order #. Either Lisi Medical Remmele's Purchase Order # shall be referenced on the cert, or a packing list referencing the Lisi Medical Remmele Purchase Order # and mill cert Heat Lot # shall be filed with the cert. Supplier shall be able to retrieve the material cert and provide Lisi Medical Remmele a copy (paper or electronic) within 24 hours of request. Lisi Medical Remmele, its Customers, and Regulatory Agencies reserve the right of access to supplier's facilities and all applicable quality records pertaining to this purchase order.

Q41 (Q41) RoHS Directive

(Q41) Restriction of Hazardous Substances Directive 2011/65/EU (RoHS) Prohibits the use of Mercury, Cadmium, Lead, Chromium VI, PBB, and PBDE in the manufacturing of product supplied to Lisi Medical Remmele. RoHS compliance must be included on every Certificate of Conformance.

Q42 (Q42) Fixed Process

(Q42) Fixed Process - Your process is an engineering controlled, pre-approved fixed process. Definition of Fixed Process: A documented method of manufacture, subject to audit, for which equipment, operation sequence, methods, parameters, and control techniques are established and approved by the end customer, and where deviations from this method may be detrimental to part quality. Requested changes must be submitted, documented as a process revision, and approved by Lisi Medical Remmele's customer before they are initiated. Only trained qualified personnel shall perform this process.

Q43 (Q43) WEEE

(Q43) Prevention of waste electrical and electronic equipment Directive 2002/96/ED (WEEE) directs the reuse, recycling and recovery of such wastes to reduce the disposal of waste in the manufacturing of product supplied to Lisi Medical Remmele.

Q44 (Q44) REACH

(Q44) Directive EC1907/2006 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) shall be adhered to in the manufacturing of product supplied to Lisi Medical Remmele.

Q46 (Q46) Animal Derivative Compliance

(Q46) Animal Derivative Compliance : Materials in use must not contain any animal or human source.

Q47 (Q47) ISO 5832-3:2012 Compliance

(Q47) Supplier is responsible for manufacturing product for this purchase order that conforms to ISO 5832-3:2012, as applicable to the work scope stated in this order. Procedures, plans, and records will be made available for review by request of authorized Lisi Medical Remmele Supply Chain representatives.

Q48 (Q48) Latex Free Requirement

(Q48) Lisi Medical Remmele products shall be manufactured, processed, and packaged in a "Latex Free" environment, and CANNOT be exposed to latex proteins. Products such as gloves, protective packaging, and adhesives used in manufacturing operations shall not contain latex.

Q49 (Q49) Conflict Mineral Compliance

(Q49) In order for Lisi Medical Remmele to comply with its reporting obligations under the Dodd-Frank Wall Street Reform and Consumer Protection Act, the country of origin of all gold, tungsten, tantalum, or tin supplied pursuant to this purchase order must be provided or it must be from recycled or scrap sources.

If the tungsten, tantalum, tin, or gold originated in the Democratic Republic of the Congo or its adjoining countries, Angola, Burundi, Central African Republic, the Republic of the Congo, Rwanda, South Sudan, Tanzania, Uganda, and Zambia, it must have been smelted by a conflict-free smelter certified by the Conflict-Free Smelter Program of the Conflict-Free Smelter Initiative. Each certification shall include the following statement: “The [mineral] supplied pursuant to this purchase order came from recycled or scrap sources or came from recycled or scrap sources or did not originate from the Democratic Republic of the Congo or its adjoining countries, or if it did, it was smelted by a conflict-free smelter certified by the Conflict-Free Smelter Program of the Conflict-Free Smelter Initiative”.