Oberg Industries
PASSION FOR PRECISION MANUFACTURING

Oberg MEDICAL
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Flowdown Requirements

1. PURPOSE

1.1 This document, when signed by the Quality Management Representatives of both companies, establishes a mutual understanding, as a matter of record, regarding authority and operation of elements of the quality management systems of "SUPPLIER" and Oberg Industries.

2. SCOPE

2.1 This Supplier Quality Agreement applies exclusively to those materials, products and/or services that "SUPPLIER" receives processes, delivers and/or provides on behalf of Oberg subject to approved work orders, purchase orders and/or contracts.

2.2 This Supplier Quality Agreement is written in compliance with the requirements of all applicable Quality System Regulations including 21 CFR Part 820, ISO 13485, ISO 9001, AS9100, and ISO/TS 16949.

2.3 All requirements of the stated (section 2.2) documents are not documented verbatim and in whole throughout this SQA. The default to the extent of a quality system requirement or interpreting a quality system requirement will utilize (section 2.2) documents as the final decision.

3. QUALITY SYSTEM REQUIREMENTS

3.1 If "SUPPLIER" is ISO certified or FDA registered or NADCAP certified; "SUPPLIER" shall maintain this status. Information on "SUPPLIER" quality management system status, including copies of certificates, and any changes to that status, shall be provided to Oberg.

3.2 Upon request, "SUPPLIER" shall grant Oberg Industries access for inspection/audit of its facilities, quality management system, records, and its production/inspection/testing processes used for the production and/or servicing of Oberg. This includes right of access by Oberg's Customers and Regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records. Oberg will provide a minimum of 24 hours notification prior to the requested visit date. Product verification is not evidence of effective subcontractor Quality Control and does not release the "SUPPLIER" from subsequent inspections and possible rejection.

3.3 Oberg Industries will be notified in writing of any proposed change to either of the following:

- 3.3.1 manufacturing process,
- 3.3.2 inspection or test process
- 3.3.3 product,
- 3.3.4 materials
- 3.3.5 facilities (location).

"SUPPLIER" is not permitted to execute the proposed change until proper authorization is granted by Oberg Industries. Approved changes to the "SUPPLIER" process' may require the submission of a new PPAP/FAI (Oberg' Customer documentation submission) and/or written approval from the end user before any changes can be made.

4. CONTROL OF QUALITY RECORDS

4.1 "SUPPLIER" is responsible for maintaining quality system records within their facility.

4.2 Manufacturing Records (known in the medical device industry as Device History Records (DHR)) will be compiled for each product/service manufactured and/or packaged for Oberg Industries.

4.3 Documentation/Records for each Oberg Industries product/service must be maintained by "SUPPLIER" and must be made readily available to Oberg. With the exception of the caveats added in 4.3.1 and 4.3.2, document/record retention periods are to be agreed upon prior to accepting the first purchase order.

4.3.1 For Medical device related components or processing a minimum retention time of 55 years shall be applied.

4.3.2 For Aerospace related components or processing the minimum retention time will be stated on each Purchase Order you receive. Retention times can vary significantly depending upon the "status" of the product and the end Customer served; "Flight Safety" or "Flight Critical" components can demand retention times of 30 years to 70 years. Retention periods of no less than 15 years shall be applied.

Oberg Industries maintains records of all supplier certifications for the minimum retention times specified by their Customers' and Federal/State/Local Government requirements. Whilst it does not obviate the need on the part of the supplier to maintain their own certifications (as well as other records), Oberg takes the responsibility to request and maintain supplier certifications (only) on file for the required minimum retention period.

5. TRAINING

5.1 "SUPPLIER" personnel performing work affecting product / service quality shall be competent based on their education, training, skills and experience.

5.2 Training of "SUPPLIER" employees, evaluation of its effectiveness and maintenance of records of that training will be done according to established "SUPPLIER" procedures. As applicable, training will include information on product/service defects and their impact on the final product.

6. PLANNING

6.1 "SUPPLIER" will implement and maintain a risk management system to cover applicable hazards/risks from their process.

7. CONTRACTS

7.1 The "SUPPLIER" must maintain a system for initiating, reviewing, processing, amending and fulfilling contracts. Contracts will be in the form of Purchase Orders; "SUPPLIER will retain records demonstrating review and acceptance of Oberg purchase orders.

8. PURCHASING

8.1 Proposal by "SUPPLIER" to use subcontractor to perform operations or tests directly affecting Oberg product must be approved in writing by Oberg prior to implementation, Oberg will provide a quality plan for the "SUPPLIER" to impose/transcend to the subcontractor.

9. PROCESS CONTROLS

9.1 "SUPPLIER" is responsible for establishing and maintaining process controls as necessary to manufacture Oberg product to predetermined specifications.

9.2 "SUPPLIER" will perform validations as necessary based upon Industry requirements. Processes that cannot be subsequently verified without utilizing destructive testing require validation.

10. HANDLING, STORAGE, PACKAGING, PRESERVATION and DELIVERY

10.1 Unless otherwise specified in writing by Oberg Industries, handling, packaging, preservation and delivery of Oberg materials and product are subject to "SUPPLIER" procedures, from receipt of material through shipment of materials or products out of the "SUPPLIER" facility. This includes materials, gages, and equipment provided to "SUPPLIER" by Oberg for aid in manufacturing or inspection of products.

11. PRODUCT IDENTIFICATION and TRACEABILITY

11.1 "SUPPLIER" is responsible for establishing and maintaining adequate procedures for control of product or material provided by Oberg, and to preserve its identity, traceability, acceptance status, and quality attributes while in the supplier facility, and throughout all operations or holding of the materials/product by "SUPPLIER".

11.2 For materials received by "SUPPLIER" from Oberg or "OTHER SUPPLIER'S", "SUPPLIER" should use the original manufacturer's lot number throughout processing to maintain traceability of the material. In the event that a lot number is not present upon material receipt, 'SUPPLIER" is responsible for generating an incoming lot number in accordance with "SUPPLIER" procedures.

12. CONTROL of INSPECTION, MEASURING, and TEST EQUIPMENT

12.1 "SUPPLIER" inspection, measuring and test equipment employed in operations affecting Oberg products will be controlled, maintained and NIST traceable through "SUPPLIER" established procedures. When external laboratories are used for inspection, test or calibration services Oberg may request the use of only ISO/IEC 17025 accredited sources.

13. MEASURING and MONITORING

13.1 "SUPPLIER is responsible for receiving and using only "ACCEPTED" materials/products.

13.2 Oberg can mandate to the "SUPPLIER" any inspection and testing needs for the manufacture of Oberg product.

13.3 "SUPPLIER" will validate inspection and test methods when requested through Oberg.

13.4 All Oberg products will receive an applicable final inspection and/or test.

13.5 "SUPPLIER" inspection and/or testing of Oberg product will be documented and become part of the manufacturing (Device History Record for Medical) of the subject part, in accordance with the requirements of section 4.

13.6 Where conformance to requirements cannot be directly verified, a Certificate of Conformity will be required.

13.7 Supplier product may be subject to incoming inspection, to ensure conformance to specifications and documentation requirements, unless a delegation of inspection authority agreement or a dock to stock program is in place (Aerospace/Automotive).

14. INTERNAL QUALITY AUDITS

14.1 Both companies will follow their procedures for defining and maintaining a program for internal and external (supplier) audits.

14.2 "SUPPLIER" is responsible for maintaining the audit schedule and associated activities as part of their internal audit procedure.

14.3 "SUPPLIER" may be subject to audits by Oberg as part of the Oberg supplier audit program. "SUPPLIER" will audit their suppliers, including subcontractors that could affect Oberg product quality/on time delivery. "SUPPLIER" will make applicable audit reports available to Oberg and allow Oberg the opportunity to join "SUPPLIER" on supplier audits should Oberg request.

15. CONTROL of NONCONFORMING PRODUCT

15.1 "SUPPLIER" must maintain a system for identification, quarantine, and disposition of nonconforming materials.

15.2 "SUPPLIER" disposition of nonconforming material for use in Oberg product must be approved by Oberg Quality Assurance.

15.3 "SUPPLIER" will notify Oberg in writing of any proposed deviations from specifications. Deviations require a written response from Oberg prior to material/product use.

16. CORRECTIVE and PREVENTIVE ACTION

16.1 Oberg identified problems, which are "SUPPLIER" liability issues will be entered into Oberg CAPA system, and forwarded to the "SUPPLIER" for participation in resolving the problem in a timely and documented manner. If the "SUPPLIER" does not respond to corrective action requests in a timely and effective manner, they may be subject to business consequences. These consequences can include removal of "SUPPLIER" from the approved supplier list, withholding of payment, and/or legal actions as appropriate.

17 CONFIDENTIALITY/ NON-DISCLOSURE

17.1 Oberg and the "SUPPLIER" will adhere to the requirements of any non-disclosure agreements in place. In the absence of a current non-disclosure agreement between Oberg and the "SUPPLIER", both parties will keep any information shared between the two parties confidential. Specifically, no drawings, specifications, process information, manufacturing details, customer information, pricing or conversations relative to Oberg or Supplier specific processes or products will be shared with or forwarded to anyone outside the organizations. This does not apply to information required by Oberg's Customers as part of product certification/verification activities.

SUPPLIER QUALITY AGREEMENT APPROVAL SIGNATURES			
Exceptions to Above Listed Requirements:			
Justification for Exceptions:			
"SUPPLIER" Quality Management Representative:	**Date:**	**Oberg Management Representative:**	**Date:**

Supplier Name:	
Supplier Address:	

REVISION LEVEL	REVISION MADE BY	DATE	REVISION DETAIL
1	D Felack	6/23/2011	Copied and edited from Form F-74-01-03 (A) to incorporate AS9100/TS16949; Change Control and NDA requirements
2	C M Truman	11/22/2011	Added "This includes right of access by Oberg's Customers and Regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records: to paragraph 3.2 to comply with AS9100 standard.
3	C M Truman	12/10/2013	Modified section 3.3 adding in changes to "product" and "facilities" (location) and end user approval. Added 4.3.2 – Aerospace product/process minimum record retention periods. Added Oberg accepted responsibility to ensure records are made available from suppliers and maintained on file for the minimum retention periods.
4	C M Truman	01/30/2014	Added text into 10.1 and 13.5

Aerospace Quality Flow Down Requirements:

In addition to the requirements stated in the existing Oberg Supplier Quality Agreement in effect with your organization, (Document OI-PUR-F-7.4-03), the following requirements / statements are incorporated as additional flow down requirements as part of the Aerospace Manufacturing Requirements.

Providing Test Samples/Coupons: Requirement to provide a test sample or coupon of raw materials for third party validation. This test coupon must be from the same batch, lot, heat number ordered. This will be appropriately noted on the Oberg purchase order for raw materials.

Counterfeit Parts Prevention: Sellers and their sub-tiers must have a counterfeit parts prevention program in place that meets the requirements of AS-6174 and AS-5553. Seller agrees not to deliver confirmed or suspected counterfeit work to Oberg Industries, or its customers. Seller shall immediately notify Oberg Industries, of any confirmed or suspected counterfeit work that has been delivered.

DFAR Requirement: All metals provided as part of this PO must meet applicable requirements of DFAR 252.225-7000.

Flow Down Requirement: All quality requirements stated in this document or on any Oberg purchase order are to be flowed to any sub- tier supplier in the supply chain for this order.

Personnel: All personnel at seller or seller's sub tier supply shall be aware of their contribution to conformity of the product or service, product safety and ethical behavior.

Supplier Performance: All suppliers to Oberg Industries are measured on quality and delivery. Targeted goals for performance are: Quality <1000 PPM and Delivery >92%. Continued performance below these stated goals with no evidence from the Supplier's of actions taken to correct, may result in the issuance of a Supplier Corrective Action Request (SCAR).

Note:
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Acceptance and performance on Oberg Purchase Orders is recognized as your compliance with the Supplier Quality Agreement (Document OI-PUR-F-7.4-03) and these additional flow downs.

REVISION LEVEL	REVISION MADE BY	DATE	REVISION DETAIL
1	D Felack	10/12/2017	Initial Release