



Realized Manufacturing
879 S. Progress Dr.
Medina, Ohio 44256
(330) 353-8877

STANDARD REMARKS

- 1) The SUPPLIER agrees to inform Realized Mfg. of any change(s) to a specification, method, process or procedure, which could potentially affect the quality of the device(s) and/or service(s). This includes changing of subcontractors for services outsourced by the SUPPLIER. This change(s) must be verified or, where appropriate, validated and all changes must be approved per 21 CFR, Sections 820.70 and 820.75, ISO 13485:2016 section 4.1.5 and by the Quality Manager, Realized Mfg.
- 2) Supplier Change Notification applies to the following changes to Process(es) or Products as applicable to:
 - a) Changes in Process and Equipment Validations
 - b) Changes in Materials necessary for the manufacture of products unless otherwise specified on Purchase Orders
 - c) Changes in a Sub-Tier supplier of materials or components
 - d) Changes in product final acceptance test issue

Realized Mfg. requires prior authorization and notification of these changes in writing before implementing.

- 3) Certifications (“Certs”, “CoC”)
 - a) Provide a certificate of conformance with the all the appropriate compliance standards/specifications noted for each production lot/serial number.
 - b) Additionally, provide a certificate of conformance (if applicable) for any special process, raw materials used.
 - c) Each certificate must show evidence/ signature of approval by a designated quality person(s).
- 4) Nonconforming Product
 - a) Provide immediate traceable notification when nonconforming product is detected in-house and/or after delivery.
 - b) Any rework to product must be to an approved procedure and approved by Realized Mfg.. Records of rework must be maintained with the lot documentation.
 - c) The Supplier is responsible for resupplying conforming product unless concessions are approved by Realized Mfg. or their customer.
- 5) Use of Subcontractors
 - a) If subcontractors are used in the production of Realized Mfg. product:
 - b) The subcontractor must be qualified and maintain a documented quality management system;
 - c) Inform Realized Mfg. as to which processes are subcontracted;
 - d) Hold all subcontractors to the requirements in these terms.

Form: QSF-742-6 Purchase

Order Rev. 1

Customer PO

- 1) The customer PO must match quote for quantity and pricing.



- 2) This quote is based on the prints provided. If revisions to prints are made, Realized Manufacturing, LLC reserves the right to re-quote based on those prints and any other new information provided to us.
- 3) Lead-time is subject to change and based on Realized Manufacturing, LLC capacity at the time of order. Delivery Dates in effect after receipt of Purchase Order, Final Prints, Solid Models, and Inspection Criteria. Realized Manufacturing, LLC reserves the right to ship products in advance of customer delivery requirements.
- 4) Purchased orders placed with Realized Mfg. will incur a cancelation fee equal to 20% for each week starting from receipt of order.
 - a) Purchase orders canceled after five (5) weeks will require full payment of order and or reimbursement for any custom tooling, fixturing and outside services that were incurred.
- 5) Payments are due within the terms of the agreed upon vendor terms.
 - a) A 6.5% interest charge per month will be applied to overdue accounts.