



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