SUPPLIER QUALITY AGREEMENT – DCN 4142, Rev 0

This Supplier Quality Agreement (the "Agreement") is entered into by and between Lancaster Metals Science Corp. and _____ ("Supplier"), a company with its production and service location(s) at:

_____

_____("Address").

1.0 General

1.1 Quality Policy & Objectives - Lancaster Metals Science Corp. and all its personnel are committed to meeting or exceeding all applicable requirements in its manufacture of metal components including zero defects and on-time delivery. Lancaster Metals Science Corp., Inc. is committed to maintain the effectiveness of the Quality Management System through continuous improvement.

1.2 Purpose -The purpose of this "Agreement" is to support our mission, quality policy, and quality objectives by defining the terms for which externally provided processes, products, and services (collectively "Product") will be established, controlled, and maintained for the manufacturing, subcontracting and shipping of "Product" for Lancaster Metals Science Corp. Lancaster Metals Science Corp. is required to control external providers (collectively "Suppliers") of "Product" to ensure conformance to Lancaster Metals Science Corp's defined specifications and all regulatory requirements applicable to the intended use of the "Product" provided. Since Lancaster Metals Science Corp. depends on its suppliers to provide compliant "Product" (including record maintenance, records, raw materials, components, storage, handling, labeling, packaging, shipping, etc.), mutual cooperation and agreement in implementing the quality requirements established within this "Agreement" is essential.

1.3 Scope - This agreement applies to all externally provided processes, products, and services for Lancaster Metals Science Corp. The scope of this agreement is intended to ensure initial and on-going production orders are adequately planned and appropriate controls are established.

1.4 Quality Management System Requirements

1.4.1 ISO 9001 – Quality management system requirements (preferred).

1.4.2 ISO 13485 – Medical device quality management system requirements (where applicable).

1.5 Definitions:

1.5.1. Lot or Batch – Components that consist of a single type, model, class, size or composition that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

1.5.2. Process Validation – Establishing by objective evidence that a process consistently produces a result or product meeting its predetermined requirements.

1.5.3. Regulatory Requirement – all applicable federal, state, and local laws, statutes, acts, ordinances, rules, codes, standards, guidelines and regulations, applicable to the Supplier and the "Product" provided under "Agreement" including but not limited to requirements for labeling, re-labeling, packaging, manufacturing, records, storage, handling, and transport of "Product".

1.5.4. Special Process – Any process for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement.

1.5.5. Validation – Establishing by objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

1.5.6. Verification – Confirmation by examination, measurement and provision of objective evidence that the specified requirements have been fulfilled.

1.6 General requirements

1.6.1 The Supplier agrees to implement appropriate quality system controls to ensure "Product" provided meets any sector specific regulatory requirements and specific requirements defined by Lancaster Metals Science Corp.

1.6.2 The Supplier shall provide a copy of the supplier's certificate(s) of registration(s), accreditation(s), and/or license(s) of its QMS standards, regulatory listings, or any other applicable certificate requested by Lancaster Metals Science Corp. Updates to certificates must also be provided to Lancaster Metals Science Corp. when received by the Supplier.

1.6.3 The Supplier shall communicate any change to the supplier's QMS or regulatory registration status without undue delay to Lancaster Metals Science Corp.

1.6.4 The Supplier shall allow Lancaster Metals Science Corp. access to review and inspect processes, equipment, and facilities used in or in relation to the production, manufacturing, packaging, testing, labeling, storing and shipping of the "Product" provided, including reports, records, and any supporting documents.

1.7 Records

1.7.1 The Supplier shall retain all required quality records related to each unique "Product" provided to Lancaster Metals Science Corp. for a minimum of fifteen (15) years after the last shipment of the production lot.

1.7.2 As applicable, required records shall include; but are not limited to Quality Manuals, Procedures, Work Instructions, Forms, Regulatory compliance records, etc., such as:

1.7.2.1 Engineering or process change control records

1.7.2.2 Product specification change approvals

1.7.2.3 Process equipment, method, or parameter change approvals

1.7.2.4 Purchasing records, purchase orders, drawings, specifications, terms, and agreements.

1.7.2.5 Material certifications for each purchased material lot.

1.7.2.6 Inspection reports, Certificates of Conformance (COC), Certificates of Analysis (COA), etc.

1.7.2.7 Incoming inspection results for purchased “Product.”

1.7.2.8 Production and service provision records (batch, device history records).

1.7.2.9 Product traceability and lot identification records.

1.7.2.10 Process and software validation records.

1.7.2.11 Installation and servicing records.

1.7.2.12 Calibration and measuring equipment adjustment records.

1.7.2.13 Test and inspection results for manufactured product.

1.7.2.14 Non-conforming product, concession justification, and rework records.

1.8 Supplier’s quality representative - The Supplier shall assign a quality representative for the duration of this agreement and this individual shall be responsible for overseeing Supplier activities that impact Lancaster Metals Science Corp.’s “Product”.

1.9 Training - The Supplier shall ensure that personnel performing work affecting product quality (including temporary employees) shall be competent on the basis of appropriate education, training, skills and experience. As part of their training, personnel shall be made aware of "Product" defects and potential failure modes which may occur from the improper performance of their job responsibilities.

2.0 Work environment- Where "Product" is handled, stored, labeled, or otherwise processed, the Supplier shall maintain a work environment that is orderly and suitably designed to meet the "Product" requirements.

2.1 Planning of product realization

2.1.1 The Supplier shall plan, develop and document the processes needed for product realization. These processes must consider intended use, sector specific requirements, industry & customer expectations, and applicable regulatory requirements to meet the quality objectives and requirements for the product.

2.1.2 The Supplier shall comply with “Product” specifications provided to supplier, either by purchase order, subsequent drawings, or referenced specification.

2.1.3. The Supplier shall agree to the terms of Lancaster Metals Science Corp.’s purchase order, and confirm “Product” quantity, pricing and firm delivery dates by submission of

an order acknowledgment.

2.1.4 If “Product” processes are new or changed, the Supplier shall enquire if part qualification or process validations activities are required.

2.2 - Change & Deviation Control

2.2.1 The Supplier shall implement no change or deviation which may affect “Product” specifications without notification. A change is defined as a difference in methods, process, or specifications beyond normal maintenance, adjustment, or calibration.

2.2.2 The Supplier shall not transfer any operation for the Product to third parties or other sites or facilities without prior written agreement.

2.2.3 The Supplier shall notify and submit a notification of planned change 90 business days prior to the implementation of the change.

2.2.4 Purchasing process - The Supplier shall establish criteria for the evaluation and selection of its suppliers and shall maintain an approved supplier list. The Supplier shall monitor and re-evaluate its suppliers annually and maintain an approved supplier list.

2.3 Validation of processes for production and service provisions - The Supplier shall document procedures for validation of processes which conform to applicable sector specific ISO 13485 QMS requirements for the intended sector of the product or service.

2.4 Traceability - The Supplier shall document procedures for product identification and identify product by lot ID throughout product realization. The Supplier shall clearly identify the product and/or its packaging with this ID. The Supplier shall ensure that “Product” lots are never mixed. The Supplier shall ensure that the unique supplier lot ID is traceable to the Lancaster Metals Science Corp. purchase order requirements. The Supplier shall include the unique supplier lot ID on all other required traceability records.

2.5 Certificate of Conformance - The Supplier shall submit a Certificate of Conformance (COC) with each shipment and with sufficient information to trace shipment back to the raw material source, subsequent testing, chemical analysis, and/or mechanical property performance results.

2.6 Complaint Handling

2.6.1 The Supplier shall document procedures for timely complaint handling in accordance with applicable ISO and regulatory requirements, and industry standards through non-conformance reports, corrective action reports, etc.

2.6.2 The Supplier shall investigate complaints if requested to do so by Lancaster Metals Science Corp. In such a case the Supplier shall submit an investigation report and action plan to Lancaster Metals Science Corp. within ten (10) business days after Lancaster Metals Science Corp’s request for an investigation, unless otherwise agreed in writing by

Lancaster Metals Science Corp. The Supplier shall record all actions taken, verification of the effectiveness of all actions taken, and any deviations to original action plan submitted to Lancaster Metals Science Corp.

2.7 Required reporting to Lancaster Metals Science Corp. - The Supplier shall notify Lancaster Metals Science Corp. within one (1) business day if the Supplier recalls or places a hold on any component that Lancaster Metals Science Corp. purchases.

2.8 Monitor and measurement of processes - The Supplier shall apply suitable methods for monitoring and measurement of validated processes and records shall be maintained.

2.9 Monitor and measurement of product - All inspection, measuring, and testing conducted by the Supplier shall be in accordance with defined requirements. The Supplier shall utilize only calibrated instruments and equipment and must maintain calibration records for review.

3.0 Control of nonconforming product - If the Supplier suspects non-conforming product has been or may have been shipped to Lancaster Metals Science Corp., the Supplier shall contact Lancaster Metals Science Corp.'s Quality Manager and Manufacturing Engineer within one (1) business day.

3.1 Rework

3.1.1 The organization shall perform rework in accordance with documented procedures that take into account the potential adverse effect of the rework on the product.

3.1.2 The Supplier shall not plan or perform any rework or repair activities, including repackaging or relabeling, related to any nonconforming "Product" without prior permission from Lancaster Metals Science Corp.

3.1.3 After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

3.1.4 Records of rework shall be maintained.

3.2 Improvement

3.2.1 The Supplier shall establish and maintain a corrective and preventative action procedure which conforms to the requirements defined within this agreement and any applicable sector specific ISO QMS or regulatory requirement.

3.2.2 Corrective and preventative action records shall be retained and shall be made available upon request by Lancaster Metals Science Corp.

End of Document

Revision	Change Description	Initial/Date
0	Original Release of Document	