1.0 SCOPE and PURPOSE:

1.1. This document defines the minimum Supplier Quality System requirements for quality of product, material or services supplied to Micropen.

1.2. The purpose of this Supplier Quality Requirement (SQR) is to specify Micropen's overall requirements for its suppliers. This document and its content shall apply to all potential and incumbent suppliers who are qualifying or currently providing goods and services to Micropen.

2.0 RESPONSIBILITY:

2.1. If a supplier has any question or concerns regarding the content of this document, they should contact Micropen's Purchasing department.

2.2. Suppliers are responsible for adhering to the SQR. Failure to meet these requirements may result in the loss of existing and/or future Micropen business.

2.3. Suppliers are expected to comply with documented material/technical specific requirements.

2.4. The Supplier's Quality System shall conform to the Requirements specified on the Purchase Order and outlined in this document. Any changes to the Supplier's Quality System that could affect conformity of the product shall be submitted to Micropen for approval prior to shipment of the product.

3.0 QUALITY SYSTEM REQUIREMENTS:

3.1. Supplier shall maintain a Quality Management System (QMS) suitable to the products and services provided to Micropen, that is certified by an accredited third-party certification body to the later version of one or more of the following, as applicable:

3.1.1. AS9100 – QMS Requirements

3.1.2. ISO 9001 – QMS Requirements

3.1.3. ISO 13485: QMS Requirements (Medical)

3.1.4. ANSI/NCSL Z540 or ISO/IEC 17025 – Measurement Management System

4.0 ORDER OF PRECEDENCE

4.1. The order of precedence of documents that set out the product requirements imposed upon and agreed to by the Supplier and which are incorporated in the purchase order is listed below. All of these items may or may not be included in any single purchase order.

4.1.1. Purchase order

4.1.2. Product drawings and specifications, i.e., those documents that define the requirements for the product to be furnished

4.1.3. Federal, military, industrial or technical society material/process specifications and standards

4.1.4. Product data forms

4.1.5. Equipment manufacturers operating procedures

5.0 GENERAL REQUIREMENTS:

5.1. Use of Customer Designated Sources

5.1.1. When required, use customer designated or approved external providers including process sources.

5.2. Contract Review

5.2.1. The Supplier shall have a written procedure(s) for reviewing Micropen Purchase Order Requirements, including PO changes/modifications, ensuring they are understood, communicated to appropriate organizations within the business and with sub-tier suppliers, where appropriate.

5.2.2. The Supplier shall notify Micropen promptly, in writing, of all changes that may affect fit, form, function, availability or reliability of the product prior to shipment. (Examples include marking, packaging or packaging method, test requirements or test method, design, material, process, and/or software).

5.3. Special Processes

5.3.1. When special process specification (ex. anodize, heat treat, plating, soldering, x-ray, cleaning, welding, or magnetic particle and penetrant inspection) are used, the supplier shall have special processes approved by Micropen quality assurance, unless the special process supplier is NADCAP certified. The supplier is responsible for maintaining a system to control such special processes whether performed at their facilities or at a lower-tier facility. The Supplier shall perform systematic, periodic evaluation of personnel, equipment, methods, and material required in these special processes to ensure positive control at all times. Objective evidence of these evaluations shall be made available to Micropen upon request.

5.4. Control of Sub-Tier Suppliers

5.4.1. If the Supplier and/or Product Manufacturer employs a sub-tier supplier to supply material or services, the Supplier shall verify that the material or service meets Micropen's Purchase Order requirements through inspection.

5.4.2. The Supplier is responsible for flowing down any applicable requirements including customer requirements to their sub-tier supplier.

5.5. Control and Release of Micropen Furnished Documents

5.5.1. Any information supplied by Micropen shall be deemed to be confidential and may not be redistributed by the supplier without obtaining prior written consent of Micropen.

5.6. Supplier Change Request

5.6.1. Supplier shall not change any drawing, process, material, or procedure without prior Micropen written approval, if such drawing, process, material, or procedure was

originally approved by Micropen. Failure to notify Micropen of these changes may result in rejection of the material.

5.6.2. Supplier shall not change any process, material, or procedure that were used to qualify items, or which was used by Supplier to become a qualified source, without written approval by Micropen.

5.6.3. Supplier shall provide written notice of planned product discontinuation.

5.7. Awareness

5.7.1. Ensuring supplier personnel are aware of:

5.7.1.1. Their contribution to product or service conformity

5.7.1.2. Their contribution to product safety

5.7.1.3. The importance of ethical behavior

5.8. Limited Life Item

5.8.1. The Supplier shall have an established process to ensure materials and components having limited calendar, operating, or cycle life shall be identified and controlled to preclude use of expired items.

5.9. Control of Non-Conforming Material

5.9.1. It is a general expectation of Micropen, that all Suppliers have documented and established processes for identifying, containing, and disposing of non-conforming direct materials (both front end and back end). This is intended to prevent non-conforming material or Product from reaching and impacting Micropen. Micropen expects cooperation from its Suppliers in providing lot numbers, batch numbers, manufacturing dates or any other pertinent information to help ensure with the segregation of suspect or non-conforming materials.

5.9.2. Prior to shipment of any identified non-conforming materials, the Supplier must notify Micropen. Any disposition other than scrap or rework requires Micropen approval.

5.10. Counterfeit, Fraudulent and Suspect Item Prevention

5.10.1. The supplier shall have an established process for the prevention of Counterfeit Components/Parts from being sold to Micropen as follows:

5.10.1.1. The supplier shall provide counterfeit component/parts awareness training to its personnel. The supplier may develop their training program based on counterfeit awareness & detection information available online.

5.10.1.2. The supplier shall flow down requirements to their suppliers to reduce the risk of receiving suspect/counterfeit parts.

5.10.1.3. If suspect or counterfeit components/parts are identified/received, the process shall address the containment, evaluation, disposition, and disposal of the components/parts.

5.10.1.4. Any receipt of suspect or counterfeit production components or parts shall be reported to Micropen.

5.11. Export Control Requirements

5.11.1. *If applicable, Suppliers operating under this Program are subject to Export Controls in accordance with the Arms Export Control Act, or the Export Administration Act of 1979 or the Atomic Energy Act of 1954. As such;*

5.11.2. *Suppliers shall have a written procedure that describes controls for ensuring that only U.S. persons are allowed access to ECI/OUO information and items. At a minimum, the written procedure shall address: Access Control, Storage, Electronic Transmission, and Destruction policies as noted below.*

5.11.3. Access Control:

5.11.3.1. ECI/OUO information and items shall be maintained in a secured area to prevent inadvertent release or disclosure to foreign persons.

5.11.3.2. Foreign persons (non-US persons), including employees, consultants, visitors, and/or sub-contractors, shall be restricted from having access to ECI/OUO information and items through any means (this includes overhearing conversations, observing material or information, or otherwise obtaining access in any way.)

5.11.4. Storage:

5.11.4.1. ECI/OUO information and material shall be stored in a secured area to restrict access from foreign persons.

5.11.5. Transmission:

5.11.5.1. The Supplier is responsible for flowing down ECI/OUO requirements to their suppliers used to support Micropen's product requirements.

5.11.5.2. ECI/OUO information shall be sent through a secure method when transmitting electronically (i.e. encryption, password protection, or secure FTP site.)

5.11.6. Destruction:

5.11.6.1. ECI/OUO articles/information shall be destroyed when no longer needed as appropriate for their industry as follows:

5.11.6.1.1. Manufacturers -- documents, electronic media, models, and materials (including scrap and in-process scrap) shall be destroyed when no longer needed.

5.11.6.1.2. Service Providers – documents and electronic media shall be destroyed when no longer needed.

5.11.6.1.3. Distributors - documents and electronic media shall be destroyed when no longer needed.

5.11.6.1.4. Laboratories – documents, electronic media, and test samples (unless returned to Micropen) shall be destroyed when no longer needed.

5.11.6.1.5. Destruction shall make said items unrecognizable and shall subsequently be disposed using normal waste processing.

5.12. Control of Inspection. Measuring and Test Equipment

5.12.1. Measurement Standards and Monitoring & Measurement Devices used in support of supplied material must be calibrated using Standards traceable to NIST. Suppliers calibration program shall be consistent with ANSI/ISO/IEC 17025 or equivalent.

5.13. Conflict Mineral Policy

5.13.1. Supplier shall comply with the requirements of Dodd-Frank Act regarding Conflict Materials.

5.13.1.1. Conduct appropriate conflict minerals due diligence within your supply chain, using the OECD Conflict Minerals Due Diligence Guidelines as a framework.

5.13.1.2. Identify and take actions to mitigate any risks identified as part of this due diligence.

5.13.1.3. Provide an updated template if there are any material changes to the results of your due diligence.

*Conflict minerals are those minerals regulated by Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. They include columbite-tantalite, also known as coltan (and its derivative tantalum); cassiterite (and its derivative tin): wolframite (and its derivative tungsten); and gold.

5.14. Slavery & Human Trafficking

5.14.1. Micropen operates with zero tolerance for slavery and human trafficking, and we are committed to seeking the best practices in our business to ensure that there is no modern slavery or human trafficking. Micropen expects its supplier as well as their supply chain to hold themselves to the same high standards that surround the issues of modern slavery.

5.15. RoHS and Halogen Free Testing Requirements

5.15.1. Suppliers shall provide to Micropen chemical analysis reports from a third-party certification unit with ISO/IEC 17025 Laboratory Quality Certification for the RoHS and Halogen substances upon request.

5.16. Packaging, Labeling, Delivery and Record Retention

5.16.1. The Supplier and/or Product Manufacturer shall have a written procedure to ensure that items (product, documents, equipment, etc.) are identified and controlled to ensure proper use and maintained to prevent damage, loss, substitution, or deterioration due to handling, aging, or environmental deterioration.

5.16.2. The procedure shall also include requirements to ensure part markings are transferred when subdividing a lot, batch, etc. of a part or material. If markings or identification records need to be replaced, they shall be researched to ensure their accuracy prior to replacement.

5.16.3. The Supplier shall prepare and submit a signed certificate of conformance and test data as required by the purchase order with each shipment of product to Micropen. Product certification shall be supported by quality evidence.

5.16.4. The Supplier shall maintain records of inspection and tests for purchased and manufactured products. Records shall provide objective evidence of quality control operations performed, the results obtained, and corrective action(s) taken. Records shall be maintained by the Supplier for 3 years after shipment of product to Micropen or as agreed in Micropen's Purchase order.

5.16.5. When Micropen proposes to Accept Product based upon the Supplier's Data, the Supplier shall have an established process for maintaining the traceability between the product and the measuring and test equipment used for product acceptance.

5.17. Quality Records and Documentation

5.17.1. Micropen suppliers shall have established procedures for collecting, storing, maintaining, and disposing any quality related documents or records. These records may include raw process data, qualification data, statistical data, test or inspection data that supports quality requirements for goods or services procured by Micropen. Quality records shall be retained for a minimum of 30 calendar years unless otherwise specified and agreed upon between Micropen and the Supplier. Micropen may from time to time and in its sole discretion, require Supplier to adopt additional procedures or practices regarding management of quality requirements.

5.18. Certificate of Compliance and Packing List

5.18.1. A Certificate of Compliance is required with each shipment.

5.18.2. Certifications shall include:

- **5.18.2.1.** Manufacturer's Name
- **5.18.2.2.** Manufacturer's Address (where part or material is made)
- **5.18.2.3.** Manufacturer's cage code (if applicable)
- **5.18.2.4.** Part Number or identification as shown on the purchase order
- **5.18.2.5.** Part Number Revision (if applicable)
- **5.18.2.6.** Purchase Order Number
- **5.18.2.7.** Serial Number (if applicable)
- **5.18.2.8.** Manufacturer's lot, batch number/date code
- **5.18.2.9.** Expiration and/or cure date (if applicable)
- **5.18.2.10.** Special process and inspection/specification (including revision number) as applicable.

5.18.3. Certifications must be signed by an authorized agent of the supplier. If it is an electronic certification, an electronic signature is required from an authorized agent of the supplier.

5.18.4. Micropen may refuse delivery of items if supplier fails to submit with each shipment all documentation specified here-in.

5.19. SAFETY DATA SHEETS (SDS)

5.19.1. Supplier must provide the applicable safety data sheets with the product shipment.

5.20. Test Specimens

5.20.1. The Supplier must provide test specimens for design approval, verification, inspection, and/or auditing when requested.

5.21. Corrective Action Report

5.21.1. When a quality problem exists with supplier's items, Micropen may forward a Vendor Corrective Action Request (VCAR) to supplier. Supplier shall respond to VCAR requests within 30 business days and must include the following information: analysis of the cause of the problem, statement of the action taken to prevent recurrence, and the effectiveness of the action.

5.22. Medical Requirements:

5.22.1. In order for Micropen to furnish devices that are safe, effective and in compliance with the Federal Food, Drug and Cosmetic Act, supplier shall adhere to the following;

5.22.2. In compliance with FDA Regulations 21 CFR Part 820.50, Purchasing Controls, Supplier shall comply with section 6.0 in the general document.

5.22.2.1. At a minimum, change notification information shall consist of change description, proposed change date, affected part number(s), contact information, reason for change, and method of identification.

5.22.2.2. Associated records shall be maintained for a minimum of 15 years.

5.22.3. In compliance with FDA Regulations 21 CFR Part 820.60, Identification, Supplier shall comply with section 3.0 in the general document.

5.22.4. In compliance with FDA Regulations 21 CFR Part 820.65, Traceability, Supplier shall comply with 5.07 and 4.06.

5.22.4.1. Each package of material furnished shall contain Material with the same lot or date code and purchase order unless prior written authorization has been granted. In these cases, Micropen shall communicate and document the mutual agreement of said requirements.

5.23. Right to Access:

5.23.1. The Supplier shall allow access by Micropen, our customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information and flow down this requirement to sub-tier suppliers.