

## Ametek EMC Supplier Quality Agreement

### Ametek EMC Quality Introduction

Being a part of the growing medical device manufacturing field, Ametek EMC takes great pride in its strict adherence to its customer specifications and requirements, and expects the same from its suppliers.

### Effective Date

This quality agreement comes into effect on the date of supplier acknowledgement.

### Ametek EMC Locations and Addresses

This agreement encompasses the supplier and the following sites / locations which form Ametek EMC:

- **Technical Services for Electronics, Inc. North America Locations**
  - 7800 Equitable Drive, Eden Prairie / Minneapolis, Minnesota 55344 USA
  - 177 Industrial Parkway, Jackson, Minnesota 56143 USA
  - 10565 SW Nimbus Ave, Tigard, Oregon 97223 USA
  - Avenida Los Encinos Manzana 1 Lote 3, Parque Industrial Villa Florida, Reynosa Tamaulipas 88730 Mexico
- **Technical Services for Electronics, Inc. Asia Locations**
  - 2F, No. 21 Jiankang Road, Jhonghe Dist, New Taipei City 235, Taiwan, 23584, R.O.C
  - No. 155 PuHui Road, Jiu Ting Development Area, Building #4, Song Jiang District, Shanghai, China 201615
- **Avicenna Technology Inc.**
  - 1602 Benson Road, Montevideo, MN 56265 USA
- **Avicenna Technology Inc. DBA Laserage**
  - 3021 North Delany Road, Waukegan, IL 60087 USA
  - 1971 Milmont Drive, Milpitas, CA 95035 USA
- **Avicenna Technology Inc. DBA Venta Medical**
  - 1971 Milmont Drive, Milpitas, CA 95035 USA

### Scope

This quality agreement outlines the roles and responsibilities of Ametek EMC and its suppliers with respect to quality assurance, regulatory requirements, and delivery expectations, for the product manufactured and / or supplied to Ametek EMC.

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**Purpose**

The purpose of this supplier quality agreement is to communicate and define the basic quality system requirements and business procedures required by Ametek EMC.

The requirements within this agreement are provided as a supplement to, but do not replace, the purchase order, engineering drawings, engineering specifications, and other applicable documents.

The expectations contained within this agreement are based on Ametek EMC’s philosophy of defect prevention and continuous improvement by developing quality into products and services rather than defect detection after they have been produced.

**Confidential Information**

The supplier shall ensure that all Ametek EMC documentation is treated as proprietary and confidential, a non-disclosure must be executed between Ametek EMC and the supplier.

**Use of Third Parties**

Ametek EMC’s supplier shall not allow a third party to manufacture, package, label, inspect, test, or release product unless it has disclosed in writing to Ametek EMC and Ametek EMC has approved the use of a third party. In such a case, the supplier shall assure that the third party has been properly selected and qualified to perform the role as the supplier assumes ultimate responsibility for the performance of the third party.

**Purchase Order Changes / Authorizations**

The Ametek EMC Purchasing Agent / Buyer or Director, Global Supply Chain are the only Ametek EMC representatives who may make purchase commitments for Ametek EMC required material / services or authorize changes to existing purchase commitments. Changes made to purchasing commitments, not authorized in writing by the buyer are made at the supplier’s own risk.

**Supplier Performance Reporting**

Ametek EMC routinely evaluates the performance of its suppliers. Ametek EMC measures supplier performance based on the following two items:

- On-Time Delivery
  - Percentage of lots that were received on-time.
  - On-time is defined as being received no more than five days prior and one day past the date (non-business days included) given on the order acknowledgement.

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- Lot Acceptance
  - Percentage of lots that were accepted at Ametek EMC.
  - Accepted is defined as being accepted through receiving inspection and consumed on the production line with no supplier related issues.

Ametek EMC may also request periodic meetings to review the supplier’s performance.

**Product Quality**

Ametek EMC’s suppliers shall ensure that each shipment of their products meets the requirements of the purchase order, engineering drawings, engineering specifications, supplier quality agreement, and any other applicable documents. Approval, verification, or qualification by Ametek EMC does not absolve the supplier of this responsibility.

**Product Identification and Traceability**

The supplier shall establish a system for the control of all product and materials. The supplier shall identify product throughout the production process and ensure all operations and tests were completed. The supplier shall establish a traceability system that tracks components from raw material through inspection, test, and final release operations (including rework and outsourcing of third parties).

**Packaging and Shipping Methods**

The supplier shall ensure that all packaging and shipping methods prevent damage (cosmetic, mechanical, or other) to product. Each product must be properly labeled and identified with the following information; Ametek EMC purchase order number, Ametek EMC part number, revision, lot number, date of manufacture, and quantity. Special packaging requirements may be specified; however, it is the supplier’s responsibility to ensure the product is packaged appropriately for shipment. Barcoding is preferred however not required at this time.

**Certificate of Conformance**

At the purchasing agent’s request, a Certificate of Conformance stating the products conform to all order requirements shall accompany each shipment. The supplier shall have available for review all sub-tier certifications for goods and processes that support the shipment.

All suppliers that perform secondary processes that cannot be readily verified or can only be evaluated through destructive testing (i.e. annealing, coating, brazing, etc.) shall provide a Certificate of Conformance with each shipment.

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**Electrostatic Discharge (ESD)**

If ESD sensitive products are being supplied to Ametek EMC, the supplier must have a documented ESD system in place to ensure proper handling and packaging requirements are followed. Applicable products include circuit boards, electronic assemblies with exposed components or connectors, and semi-conductors.

**Order of Precedence**

If at any time two or more documents may conflict, the order of precedence is as follows: purchase order > engineering drawings > engineering specifications > supplier quality agreement > any other applicable documents.

When two documents are found to be conflict, Ametek EMC shall be notified so it can take steps to resolve the issue.

**Quality Management System**

The supplier shall maintain a documented quality system that encompasses the requirements of ISO 9001 at a minimum, or ISO 13485 which is preferred. Particular focus shall be placed in the following areas:

- Process Controls
- Control of Records
- Control of Documents
- Measurement and Test Equipment
- Non-Conforming Material
- Corrective Actions
- Supplier Controls

The supplier shall promptly notify Ametek EMC of any changes to any held certifications. The supplier shall promptly notify Ametek EMC of any audit findings that may affect the safety, effectiveness, conformity, or availability of product the supplier provides to Ametek EMC.

**Process Controls**

The supplier shall maintain documented process controls which define things such as: process steps, process tolerances, monitoring / measurements steps, and responsible parties' / action plans. Examples of this may be lot travelers, process routers, control plans, inspection plans, etc.

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**Control of Records**

The supplier shall maintain legible, readily identifiable, and retrievable records as evidence its products meet Ametek EMC’s requirements. The supplier shall define how it identifies, stores, protects, retains (minimum of seven years for those related to Ametek EMC), and disposes of its records.

Prior to any Ametek EMC related records being disposed, supplier shall offer Ametek EMC the option to retain them.

**Control of Documents**

The supplier shall maintain and control documents related to process controls and quality systems. The supplier’s document control methods shall ensure that only approved and issued documents are utilized.

Documents shall be legible and identifiable. When a document is obsoleted or purposefully removed from use and retained for any reason, the supplier shall have a method of identifying and segregating it to prevent accidental use.

**Measurement and Test Equipment**

The supplier shall ensure that all of its monitoring and measuring equipment used to impact the manufacturing process is suitable (accuracy and precision) for its intended purposes and is capable of producing valid results.

The supplier shall establish and maintain schedules for calibration and maintenance of the equipment. Calibration standards used for monitoring and measuring equipment shall be traceable to national or international standards.

**Non-Conforming Material**

Products delivered to Ametek EMC not meeting the requirements of the purchase order, engineering drawings, engineering specifications, supplier quality agreement, and any other applicable documents are labeled as non-conforming product. Examples include (but are not limited to):

- Dimensional measurements
- Packaging / labeling issues
- Missing paperwork or certifications
- Traceability issues
- Product delivered more than five days ahead of acknowledged delivery date

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When non-conforming product is discovered at an Ametek EMC facility and the supplier is determined to be at fault, the product may be handled in any of the following ways at the discretion of Ametek EMC:

- Reject the product and return all or a portion of it to the supplier.
- Accept the product under Ametek EMC approved deviation.
- Sort / rework the lot at an Ametek EMC facility. Ametek EMC may require supplier resources and or third party resources to support sorting / rework (which may require reimbursement).

When product is to be returned to the supplier, Ametek EMC's buyer will work with the supplier to resolve quality, supply, and billing issues. Costs associated with a return are to be absorbed by the supplier. When technical support is required, additional Ametek EMC resources may also be involved.

**Supplier Deviations**

If the supplier needs to deviate from a purchase order, engineering drawings, engineering specifications, supplier quality agreement, or other applicable documents the supplier shall document the deviation request using QFH010 including the specific deviation, the reason for the deviation, and the period (time, lots, etc.) the deviation will be in effect.

**Corrective Actions**

The supplier shall maintain a system to manage all Supplier Corrective Action Requests (SCAR) requests from initiation to completion issued to their organization. Ametek EMC may issue a SCAR for any of the following examples (but is not limited to):

- Repeat or initial non-conformances at receiving inspection
- Repeat or initial non-conformances in-process
- Repeat or initial non-conformances at Ametek EMC's customer
- Packaging / Labeling Issues
- Traceability Issues
- Delivery Issues

**Ametek EMC expectations for supplier SCAR communication:**

Initial response from supplier within 48 hours:

- Receipt of SCAR and notification of owner within supplier
- Bound all suspect product (WIP, FG, In-Transit, at Ametek EMC) and take immediate containment action
- Recovery plan to supply Ametek EMC with acceptable product

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Corrective action plan from supplier within ten business days:

- Completed root cause investigation (supplier should use and include standard problem solving techniques such as 5 whys, fishbone, is / is not, etc...)
- Confirmed / most probable root causes
- Create corrective action plan for implementation and verification of corrective actions (including relevant due dates)

Corrective action closure per plan:

- Implement corrective actions per plan
- Verify effectiveness of corrective actions per plan

**Supplier Controls**

Ametek EMC’s supplier shall maintain a system to monitor and control the activities of their suppliers, subcontractors, service providers, and / or material sources. Ametek EMC’s suppliers may flow down all or individual requirements from this agreement to their suppliers, subcontractors, service providers, and / or material sources as applicable.

**Change Control**

Proposed supplier changes, including but not limited to any material, tooling, fixture, facility (or location), and process changes which may affect form, fit, function, reliability, serviceability, performance, functional interchangeability, regulatory compliance, safety, options, spare parts interchangeability, or interface capability with Ametek EMC products must be approved by Ametek EMC prior to implementation.

The changes must be submitted a minimum of 120 days prior to implementation, and samples of proposed alternates need to be received 100 days prior to implementation whenever possible. The supplier will allow for a last time purchase to cover the time needed for change qualifications.

Proposed changes will be communicated to Ametek EMC using QFH009 and submitted through the Ametek EMC buyer.

Ametek EMC will evaluate the change request, but end use customer approval may be required before final approval is authorized. Ametek EMC has the right to request additional samples, or sample runs as dictated by the qualification / validation requirements. Ametek EMC will incur no additional costs for proposed supplier changes.

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Changes implemented by the supplier which have not been approved by Ametek EMC or which have not been communicated to the Ametek EMC buyer are made at the supplier's own risk.

**Audits and Assessments**

The supplier shall allow the Ametek EMC or its authorized representative, to perform audits of the supplier's facilities, systems, documentation and other requirements related to this agreement. Audits will be scheduled within a reasonable amount of time at mutually agreed dates and times. Ametek EMC respects the supplier's intellectual property and may agree upon confidentiality agreements / non-disclosure agreements as applicable.

Following each audit, a report shall be issued and the supplier shall issue a plan to determine correction, cause, and corrective action for each finding within thirty days of the issue date.

While Ametek shall rely on its supplier to monitor and control their suppliers, subcontractors, service providers, and / or material sources, Ametek EMC reserves the right to perform audits of any portion of said supply base to ensure product quality.

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**Supplier Acknowledgement**

Supplier Name: \_\_\_\_\_

Supplier Address: \_\_\_\_\_

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Approver Name: \_\_\_\_\_

Approver Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

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