



THE WEISS-AUG GROUP

QUALITY. PRECISION. EXCELLENCE.

Supplier Quality and Business Compliance Manual



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1.0 Introduction

1.1 About Weiss-Aug Group

Weiss-Aug Group is a division of Weiss-Aug Co., Inc.

Weiss-Aug Group is a manufacturer of components within the medical market, with advanced expertise in overmolding / injection of components.

1.2 Purpose and Scope

The purpose of this Supplier Manual is to communicate Weiss-Aug Group division's quality requirements and expectations to all new and existing suppliers. This document was developed as a baseline for qualifying newsuppliers and supporting our existing suppliers in understanding and upholding Weiss-Aug Group division's requirements and expectations.

The requirements and expectations included in this document apply to each stage related to the development, manufacture, delivery, and support of all products or services provided to Weiss-Aug Group. This Supplier Manual serves as a supplement and does not take precedence, nor serves as a replacement for pre-established agreements, engineering specifications, or Weiss-Aug Group purchase orders.

Weiss-Aug Group has suppliers with varying technologies and capabilities; the expectations stated in this manual may apply in different ways, depending on the Product or Service supplied.

1.3 Non-Disclosure Agreement

Weiss-Aug Group may ask a Supplier to sign a Non-Disclosure Agreement in certain cases where proprietary information is shared throughout the course of business with a Supplier. Weiss-Aug Group utilizes a standard Mutual Confidentiality Agreement form for this purpose.



2.0 Sustainability and Environmental Responsibility

2.1 Regulatory Compliance

Suppliers must fully understand and comply with all country and local environmental regulations for the areas in which they operate.

In addition to Weiss-Aug Group employees, we expect all of Weiss-Aug Group partners, distributors, resellers, advisors, consultants, contractors, agents and other intermediaries representing Weiss-Aug Group to adhere to our Supplier Quality and Business Compliance Manual.

2.2 RoHS Compliance, REACH, WEEE, Conflict Minerals

When required by Weiss-Aug Group division's customers, our Suppliers are expected to state RoHS, REACH, WEEE, and/or Conflict Mineral compliance on the Declaration of Compliance with each purchase order.

2.3 Environment, Health and Safety

Suppliers should be aware of how their businesses and Products impact the environment and the safety/health of employees.

Suppliers should commit to continuous environmental, safety and health improvement, including the lowering of the supplier's carbon footprint.

Provide composition information on parts/components as requested where necessary.

2.4 Business Continuity

Continuous supply of product is critical even in an emergency. To ensure consistent delivery, suppliers are expected to maintain a formal contingency plan. If required by customers or market demands, Weiss-Aug Group will work with supplier to identify any areas of risk and

develop alternate plans.

2.5 Ethics and Labor, Suppliers Sustainability

Weiss-Aug Group division require suppliers to conduct business using equal opportunity employment practices, and to comply with applicable laws and regulations on labor and nondiscrimination.

We expect suppliers to act with integrity and in compliance with high standards of business ethics, including anti-corruption or bribery, free competition.

Weiss-Aug operates following the CORE VALUES and CODE OF CONDUCT, which we expect our suppliers to adhere to:

CORE VALUES

- Customer Satisfaction
- Openness / Trust
- Fairness / Respect / Integrity
- Long-term Commitment
- Pride / Competence
- Teamwork / Recognition
- Safety / Cleanliness
- Empowerment / Risk Taking
- Proactive / Responsive
- Continuous Improvement

CODE OF CONDUCT

- Practice our Core Values
- Be Positive
- Support Consensus
- Practice Self-Control
- Seek to Understand Each Other's Point of View
- Show Respect and Uphold the Dignity of everyone
- Treat others as you would have them treat you



3.0 Business Management System

3.1 Quality Management System

Suppliers to Weiss-Aug Group must have an established and documented Quality System that includes all appropriate elements of a quality system best suited for the supplier's business management system.

The management system shall be designed to ensure: (a) compliance with Supplier Standard Operating Procedures and customer requirements related to the supplier's operations, products and services; (b) conformance with an International standard of organization quality systems (i.e. ISO 9001 or ISO 13485) or cGMP; (c) identification and mitigation of risks related to products or services provided to Weiss-Aug Group; (d) the facilitation of corrective/preventive action and continuous improvement.

3.2 Change Management

Suppliers are required to notify Weiss-Aug Group of changes made to materials, products, or processes. This should include facility changes and/or changes associated with sub-tier suppliers.

Suppliers must notify Weiss-Aug Group **prior** to implementing such changes by submitting a **process change request for approval** form or letter to Weiss-Aug Group. It is Weiss-Aug Group division's responsibility to determine whether the changes could affect the quality of a finished device.

3.3 Audit and Assessment

To ensure compliance to Weiss-Aug Group Quality Requirements, suppliers will allow Weiss-Aug Group and our customers' representatives to audit and have access to the supplier or sub-tier supplier's processes, quality systems, and facilities.

Suppliers are expected to provide a prompt response for all audit findings.

3.4 Sub-Supplier Control and Flow Down

Weiss-Aug Group suppliers must have a documented supplier management system for managing their sub-tier suppliers. The supplier management system should include appropriate QMS requirements, quality assurance practices, and quality control methodologies.

Weiss-Aug Group suppliers may be required to flow down quality requirements to their sub-tier suppliers. Suppliers are expected to monitor and measure compliance from sub-tier suppliers.

3.5 Quality Begins with Me!

Weiss-Aug Group implemented and follow the Quality Begins with Me shared accountability for product quality. We expect all employees to monitor product quality at each stage in our value chain — design, manufacturing, tooling, shipping. Quality is non-negotiable. We share four fundamental expectations: communication, training, courage, accountability.



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4.0 Quality Assurance

4.1 Qualification and Requalification

All new suppliers for Weiss-Aug Group are required to complete Weiss-Aug Group supplier qualification process. Supplier Qualification process may include: Supplier Self-Assessments, Audits, and potential Quality Agreements.

Existing suppliers for Weiss-Aug Group may be required to complete the Weiss-Aug Group requalification process which includes the review of various agreements, supplier performance, and continuous improvement. On-site audits may be conducted during requalification.

4.2 Quality Assurance Methodologies

Weiss-Aug Group expectations for quality assurance includes utilization of measurement systems and analysis (MSA), process capability studies (CP, CPK, PP, PPK), control plans, PFMEA's, as applicable for the program or project.

Supplier Quality Control procedures must ensure personnel are trained and competent to perform defined inspection and test methods.

4.3 First Articles

Suppliers are required to provide Weiss-Aug Group with First Articles submissions for new product qualification and any changes made during the product lifecycle.

First Articles inspections are used to demonstrate that all Weiss-Aug Group specification requirements are fully understood by the supplier and that the process is capable of producing products that meet these requirements during an actual production run.

4.4 Escapes

Suppliers are required to immediately notify Weiss-Aug Group in the event where products have been released by the supplier or sub-supplier and are subsequently determined to be nonconforming.

4.5 Supplier Corrective Actions

Suppliers are expected to fully cooperate with Weiss-Aug Group investigation and containment actions per Weiss-Aug Group division's Supplier Corrective Action procedure (Appendix A).



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5.0 Supplier Performance

5.1 On-Time Delivery

Suppliers are expected to deliver all orders to Weiss-Aug Group on the required date agreed upon with each purchase order.

Typically, deliveries are considered on-time when they are delivered within a four-day window of the required date of the purchase order. The four-day window includes shipments delivered two days before, one day after, and including the required date of the purchase order.

5.2 Scorecards

Weiss-Aug Group will measure supplier performance on a periodic basis. Supplier performance data will be collected and used for periodic supplier business reviews and decision making in the continuation, extension, or termination of supply.

Please Note: Acceptance of a Weiss-Aug Group division's purchase order (PO) constitutes acknowledgment that the Supplier has read and understands the expectations of this Manual.



Sustainability of Weiss-Aug Sourcing Program

<p>Environmental Health and Safety</p> <p>We expect suppliers to comply with applicable environmental, health and safety regulations and laws.</p>	<p>Human Rights and Labor Relations</p> <p>We require suppliers to conduct business using equal opportunity employment practices, and to comply with applicable laws and regulations on labor and nondiscrimination.</p>	<p>Supplier Ethical Conduct</p> <p>We require suppliers to act with integrity and in compliance with high standards of business ethics, including anti-corruption or bribery, free competition.</p>
<p>Product Quality</p> <p>We require suppliers to maintain a quality management system that is effective and complies with Weiss-Aug's and our customer's requirements.</p>	<p>Information Security</p> <p>We have implemented a security management system that controls the data, confidential information and minimizes risks within the supply chain.</p>	<p>Supplier Diversity</p> <p>We equally respect each and all employees, in the workplace and in their communities, and we extend this belief to our supply chain.</p>



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6.0 Supplier Agreement

By signing below, Supplier certifies that it has read, fully understood, and agreed with this Supplier Quality and Business Compliance Manual. Any questions concerning this Supplier Quality and Business Compliance Manual have been raised and discussed.

Supplier

Signature _____

Name

Title

Date