



MAHAR™
MAHAR Supplier Manual

Introduction

Mahar Tool Supply Company's ("MAHAR's") suppliers ("Suppliers") are expected to demonstrate their commitment to excellence in every aspect of their performance in the global supply chain. This Supplier Quality Manual ("Manual") is designed to set forth many of the expectations and requirements that Mahar has of its suppliers.

To meet our customers' world-class expectation and help them maintain the quality and regulatory compliance of their products and/or services, MAHAR has established appropriate standards to ensure the quality of our products and the integrity of our operations. This Manual is the quality standard for every MAHAR supplier worldwide. This common global Manual allows MAHAR to evaluate all suppliers around the world based on common expectations and performance standards. MAHAR considers collaboration with the supply chain an integral part of our success and, therefore, strives to operate as an integrated team with suppliers. The selection of suppliers is based not only on the quality and on competitiveness of their products and services, but also their adherence to social, ethical, and environmental principles.

MAHAR Business Philosophy

1. Purpose & Scope

The purpose of this manual is to provide MAHAR Suppliers guidance as to MAHAR's Commercial, Quality, Delivery, Technology, and Business expectations. This Supplier Manual applies to all Suppliers that supply product to the production facilities of MAHAR or directly to MAHAR's Customers. Suppliers shall pass down the requirements of this Manual, all statutory and regulatory requirements, as well as special product and process characteristics to their sub-suppliers and require the sub-suppliers to cascade all applicable requirements down the supply chain.

The demand for improved product quality is widely recognized as the primary challenge facing our industry. MAHAR has been committed to supplying the highest quality product possible. Our policy is to meet and strive to exceed Customer requirements with the standard of measurement being zero defects.

This Manual details the procedures and systems of this quality approach, the basis of which is defect prevention and continuous improvement. MAHAR is committed to this approach,

and we expect the same commitment from our Suppliers. It is important that MAHAR's supply base develops our same enthusiasm for excellence and displays the willingness to work toward the common goals outlined in this Manual. With this in mind, MAHAR has created this common Supplier Manual applicable to all MAHAR Suppliers supporting the following points:

- Communicate to Suppliers MAHAR's expectations, goals, and minimum requirements to assure quality of supplied parts.
- Encourage open and free communication of ideas, information, and notification of problems among Suppliers, MAHAR, and its customers in the spirit of teamwork and cooperation.
- Develop an overall plan to ensure smooth production at Supplier and timely delivery to MAHAR and its Customers, based on effective planning and communication.
- Define the quality assurance procedures and documents Suppliers must follow to assure application of an effective quality management system.

2. Supplier Code of Conduct

MAHAR's beliefs serve as a guide for our employees on the way we conduct our business—with our customers, our employees, our Suppliers, and our communities. These beliefs, which are deeply rooted in our culture, also serve as a framework for the standards of business conduct, we expect of any Supplier that does business with us. Further, these commitments are in accordance with the Supply Chain Due Diligence laws. Compliance with these standards will be a mandatory component of our purchase contracts worldwide and must also apply to subcontractors, in particular under the premise to protect human rights and prevent or minimize environment related risks at all times in our supply chain. It is also expected that our Suppliers cascade similar expectations described in this Supplier Code of Conduct to their own Suppliers.

a. Inclusion

MAHAR operates in a climate of respect, courtesy, and impartiality. The same fairness and impartiality should be extended to all legitimate Suppliers who wish to compete for MAHAR business. We expect open, honest, and timely communication. MAHAR Suppliers should encourage a positive and diverse workplace by not tolerating harassment or discrimination, including discrimination involving national and ethnic origin, race, color, social origin, health status, sexual orientation, religion, gender, age, political opinion, or disability.

Guiding Principles Regarding Basic Working Conditions

MAHAR expects its Suppliers and sub-suppliers to develop policies and practices for facilities worldwide, to provide working conditions that are appropriate under applicable law and that support and uphold MAHAR's beliefs, including, but not limited to, the following:

- **Use of Child Labor is Prohibited:** Suppliers are prohibited from employing any person below the age of 15 except as part of a government sponsored training or apprenticeship program.
- **Forced Labor, Corporal Punishment, and Other Prohibited Activities:** Suppliers are prohibited from using forced labor in any form and are further prohibited from physically abusive practices, including corporal punishment or the threat of corporal punishment. Supplier will abstain from conducting, directly or indirectly, any form of torture, cruel, inhuman or degrading treatment practices, war crimes, crimes against humanity, support of non-state armed groups in any activity related to the supply of goods or services to MAHAR, including but not limited to the extraction, transportation, distribution and sale of minerals, or other serious violations of international law.
- **Freedom of Association:** Suppliers must respect the rights of workers to establish and join an organization of their own selection and their rights to collective bargaining, in accordance with local laws. Workers must not be penalized or subjected to harassment or intimidation for exercising any legally protected right to join or not join such legal organizations. Suppliers must also encourage open communication between management and employees regarding working conditions without fear of retaliation, intimidation, or harassment.
- **Women's Rights:** Gender inequality underpins problems such as unequal opportunity in employment and unequal pay for equal work. MAHAR expects Suppliers to provide equal opportunity in employment and commit to equal pay for equal work.
- **Compensation:** Suppliers' employees will receive compensation and benefits that are competitive and consistent with applicable laws regarding minimum wages, overtime hours, and legally mandated benefits. The compensation paid to Suppliers' employees should constitute at least a minimum of a fair and living wage.
- **Ethical Recruitment:** Suppliers are expected to hire workers lawfully, in a fair and transparent manner that respects human rights. Suppliers should not mislead or defraud potential workers about the nature of the work, ask workers to pay recruitment fees, or confiscate, destroy, conceal, or deny access to worker passports and other government-issued identity documents. Workers should receive a written offer in a language well understood by the worker, stating in a truthful, clear manner their rights and responsibilities.

- Working Hours: Suppliers are expected to comply with applicable laws regulating hours of work.
- Equal Employment: Suppliers are expected to have written policies promoting equal employment opportunities and formal, independent practices for responding to any complaints,
- Health and Safety: Suppliers are expected to promote safe and healthy work environments for all employees and expect commitment to continually improving the same. If Suppliers provide their workers with residential facilities, they must provide clean and safe accommodations.
- Use of Private or Public Security Forces: Suppliers must not commission or use private or public security forces to protect the business if, due to a lack of training or control on the part of the company, the deployment of the security forces may lead to violations of human rights.
- Animal Welfare: Suppliers are expected to respect and to ensure that their sub-suppliers respect the five animal rights formalized by the World Organization for Animal Health (OIE) concerning animal welfare.

b. Integrity

MAHAR demands uncompromising ethical standards in all we do and say—we expect our Suppliers to do the same. Our policies prohibit the acceptance of gifts, services, or anything of such value that the good judgment of the recipient might be influenced, or that a third party might reasonably perceive as influencing that judgment. Payments of money, property, or services for the purpose of obtaining business or special consideration are prohibited. If a MAHAR employee solicits a gift or entertainment opportunity from a Supplier for their personal use, the request is to be declined. We discourage our employees from purchasing goods or services from MAHAR Suppliers for their personal use, even though paid for by the employee.

MAHAR recognizes that in some cultures, business gifts and business entertainment are considered an important part of the development of business relationships. Any gift or entertainment must be evaluated to ensure it is in the best interest of MAHAR, consistent with MAHAR policies and the law, and in accordance with local custom. But to be clear, no listing of ethical guidelines can be considered complete. Thus, it is incumbent upon those affected by this policy to avoid the misconception that if it is legal, it is ethical. Appropriate conduct must reflect good judgment, fairness, and high standards.

Anti-Bribery (US Foreign Corrupt Practices Act, UK Anti-Bribery Act of 2010, and French Loi Sapin 2)

MAHAR expects all Suppliers to comply with all laws and regulations applicable at all governmental levels worldwide. The use of corporate funds, property, or other resources for any unlawful or improper purpose is prohibited. Anti-corruption laws require that companies meet prescribed accounting and internal control standards and impose severe penalties on both companies and individuals for certain types of payments and practices. MAHAR Employees and our Suppliers may not give, promise, or authorize any payments, either directly or indirectly, to government officials in any country.

Conflicts of Interest

Conflict of interest occurs when an individual or a corporation (either private or governmental) is in a position to exploit his/her or their own professional or official capacity in some way for personal or corporate benefit. MAHAR expects Suppliers to ensure that their employees avoid and disclose situations where there is any perceived or actual conflict of interests and that decisions be based on solid business judgment unclouded by favoritism resulting from personal relations and opinions.

Anticorruption and Anti-money Laundering

MAHAR does not tolerate bribery, corruption, or money laundering under any circumstances. Bribery involves offering, giving, receiving, or requesting something of value to improperly influence a business decision and can take many forms, including money, gift cards, travel, employment (including internships), entertainment, and charitable contributions. Giving bribes to anyone, including government employees or officials, directly or through a third party, is prohibited.

MAHAR also prohibits facilitation payments, which are small payments intended to expedite a non-discretionary, routine government process or service (such as obtaining a visa or clearing goods through customs). MAHAR, its employees, and Suppliers are subject to local anti-bribery, anti-corruption, and anti-money laundering laws. If you suspect a bribe or other improper payment has been made, contact MAHAR immediately.

Fair Competition and Anti-Trust

MAHAR expects Suppliers to uphold fair competition and anti-trust standards including, but not limited to, avoiding business practices that unlawfully restrain competition; improper exchange of competitive information; and price fixing, bid rigging, or improper market allocation. An effective compliance policy and strategy enables a company to minimize the risk of

involvement in competition law infringements, and the costs resulting from anti-competitive behavior.

Financial Responsibility (Accurate Records) & Disclosure of Information

MAHAR expects that Suppliers perform their business dealings in a transparent manner and accurately reflect them in the companies' financial reports and filings. Financial responsibility refers to a company's responsibility to accurately record, maintain, and report business documentation including, but not limited to, financial accounts, quality reports, time records, expense reports, and submissions to customers or regulatory authorities, when appropriate. Books and records are expected to be maintained in accordance with applicable law and generally accepted accounting principles. MAHAR expects Suppliers to disclose financial and non-financial information in accordance with applicable regulations and prevailing industry practices.

c. Excellence

MAHAR seeks to be a leader in serving its customers, advancing our technologies, and rewarding all who invest in us. To extend our competitive position, we expect our Suppliers to relentlessly improve their own performance and to bring urgency to every business challenge and opportunity.

Data Protection and Data Security

MAHAR expects its Suppliers to implement robust data privacy and security standards that protect an individual's personal data, regardless of whether they are employees, customers, Suppliers, or job applicants. Suppliers should respect the privacy and civil liberties regarding the collection, retention, use or dissemination, as well as any other processing of personal data.

Intellectual Property

"Intellectual Property" includes inventions, patents, trade secrets, "know-how", trademarks, logos, and copyrights. Suppliers should use commercially reasonable practices to avoid the unjustified transfer of confidential technology and know-how (e.g., copyright, trademark, design, patent) and must be diligent to identify, protect, and defend our Intellectual Property as well as the Intellectual Property of customers and sub-suppliers.

Counterfeit Parts

MAHAR expects its Suppliers to develop, implement, and maintain methods and processes appropriate to their products and services to minimize the risk of introducing counterfeit materials into deliverable products and adhere to relevant technical regulations in the product design process.

Export Controls and Economic Sanctions

Suppliers must comply with and be knowledgeable of all applicable laws and regulations governing the conduct of international trade, including sanctions, export controls, boycotts, and customs, including those of the EU, the United States, and any other applicable jurisdiction (the "Export Control & Sanctions Laws"). Supplier will not violate and will not cause MAHAR to violate any Export Control & Sanctions Laws and will provide to MAHAR all information necessary to ensure compliance with the same.

Suppliers should have appropriate policies and procedures to ensure compliance with applicable export controls and economic sanctions laws and regulations of all relevant countries. If the Supplier is involved in the sale, marketing, distribution, or transportation of products or services, or the transfer of technology across international borders, the Supplier must verify that the transactions do not involve restricted individuals, companies, countries, or regions, and that the products do not require an export license or other authorization.

d. Responsibility

MAHAR is committed to good corporate citizenship and expects Suppliers to abide by all applicable employment, environmental, health, and safety laws and regulations. MAHAR will not allow the use of any forced, involuntary or child labor by Suppliers who provide goods or services to us. MAHAR is committed to prevent and minimize any risk to human rights or environment in our business areas and across our supply chain.

Rights of Minorities and Indigenous Peoples

Suppliers are expected to respect the rights of local communities to decent living conditions; education, employment, social activities; and the right to Free, Prior, and Informed Consent (FPIC) to developments that affect them and the lands on which they live, with particular consideration for the presence of vulnerable groups.

Land, Forest, and Water Rights and Forced Eviction

We expect that Suppliers avoid forced eviction and the deprivation of land, forests, and waters in the acquisition, development or other use of land, forests, and water.

Environmentally Responsible Products and Processes

MAHAR expects Suppliers to responsibly protect the environment for the benefit of society and future generations. Suppliers should strive to conserve, recycle, and reuse resources efficiently, using responsible and sustainable environmental practices, including but not limited to energy and emissions reduction initiatives, monitoring, and reporting. Suppliers should minimize water consumption, effectively reuse, and recycle water with responsible treatment of wastewater discharges and prevent potential impacts from flooding as a consequence of rainwater run-off, as required by and in accordance with applicable law.

To assure that our products and processes will provide the maximum benefit and least damage to the environment, we expect Suppliers to:

- Develop and offer products that help contribute to improved fuel efficiency and reduced emissions.
- Evaluate and minimize the complete-life cycle environmental impact of your products and processes.
- Minimize waste generation.
- Lead in the conversion to environmentally friendly materials including the use of recycled and recyclable materials.
- Maximize the efficient use of resources such as water.
- Obtain energy from renewable sources and/or lower impact resources wherever practical to reduce greenhouse gases.
- Strive for environmental leadership in regions in which you operate and fulfill the environment-related obligations set out in the Supply Chain Due Diligence laws.

Air Quality

Suppliers should routinely monitor and disclose, appropriately control, minimize, and to the extent possible, eliminate emissions contributing to air pollution, as required by and in accordance with applicable law. Suppliers should assess cumulative impacts of pollution sources at their facilities and mitigate their pollution levels accordingly.

Responsible Chemical Management

Suppliers should identify, minimize, or eliminate the use of restricted substances in manufacturing processes and finished products to ensure regulatory compliance. Suppliers should also be aware of any use of restricted substances in processes and finished products, and actively investigate suitable substitutes to maintain product and environmental stewardship.

e. Adherence

We expect your cooperation in ensuring adherence to our Supplier Code of Conduct. We expect Suppliers throughout our entire supply chain to adopt and enforce policies in accordance with those stated above. MAHAR seeks to identify and do business with organizations that conduct their businesses to these standards.

MAHAR personnel are expected to report any known or reported violations of this code to their respective supervisor without fear of retaliation. If you or anyone in your company believes that a MAHAR employee or other Supplier has violated this policy, please contact MAHAR by phone at 1-800-456-2427, or e-mail to supplychain@gomahar.com.

f. Due Diligence in Supply Chains

In accordance with the applicable Supply Chain Due Diligence laws, all Suppliers are expected to fulfill their obligations to prevent and minimize any risks to human rights and the environment or to end any such violation. Suppliers are responsible for ensuring their sub-suppliers act in compliance with the requirements of the Supply Chain Due Diligence laws.

MAHAR also seeks to identify possible adverse effects on and risks to human rights and the environment, both internally and externally, through ensuring ISO compliance and reviewing the origin of products and/or services. In the event a risk is identified, MAHAR strives to implement preventive measures and take remedial action.

3. Supplier Manual Access

a. MAHAR's Responsibility

- Provide Supplier access to the latest released version of MAHAR's Supplier Manual on Mahar's website or upon request.
- Update Supplier Manual as required.

b. Supplier's Responsibility

- Use the current released version of MAHAR's Supplier Manual available on Mahar's website.
- Frequently visit MAHAR's website to determine whether Supplier is in possession of the most current released version of MAHAR's Supplier Manual.
- Provide training to personnel regarding the location of the controlled version of MAHAR's Supplier Manual.
- Ensure that MAHAR has the correct Supplier contact information allowing notification of any changes.

c. Revisions

Any updates to the Supplier Manual will be made available to Suppliers on MAHAR's website.

Quality Principles

4. Quality Management Systems

Supplier will maintain a compliant and certified/registered Quality Management System based on the product provided. Examples of Quality Management Systems include ISO 9001 and ISO 13485 (with certificate referencing the IAF mark). ISO 17025 (with the certificate referencing the ILAC MRA mark). The FDA cGMPs, including, but not limited to, 21 CFR Part 820, 21 CFR Part 58, and 21 CFR Part 1271 shall be demonstrated by the FDA registration or audit reports with records demonstrating the review and verification of all objectives.

The supplier quality system review is part of the initial and ongoing assessments performed by MAHAR. Changes from an existing quality system pertaining to registration/certification and the supplied product or service will require Supplier to notify MAHAR in writing prior to the implementation of the change.

Supplier shall submit updated ISO certifications with any updates or re-certifications to supplychain@gomahar.com.

All applicable elements of a quality system are considered when MAHAR is making its determination whether a quality system is acceptable, including, but not limited to, the following:

- Requirements for qualification of supplier's personnel

- Properly implemented quality procedures for production processing including validation
- Appropriate statistical techniques to analyze quality data and production effectiveness.
- Corrective and preventive action system with evidence that actions are effective in preventing and eliminating defects. These actions will be part of a continuous improvement action.

5. Audits

Supplier will permit MAHAR or its designee to audit Supplier's quality management system upon receipt of advance written notice.

- Supplier will be available to participate in quality assurance meetings at either the Supplier or MAHAR's facility to review and update the status of issues pertaining to product or process quality and reliability for the processes, services, and/or products purchased by MAHAR.
- Supplier will grant all relevant third parties to whom MAHAR is accountable access to its works to audit the Supplier's facility and/or records, with or without issuance of advance notification by the third-party organizations.
- Supplier will notify MAHAR, via written correspondence to supplychain@gomahar.com, of any regulatory body IE. FDA of an inspection that is scheduled or initiated in their facility.
- Supplier will provide required details of any actions (e.g. correction, removal, FDA 483 or other regulatory inspection findings, any warning letter issued by FDA, etc.) that impact the products and/or services Supplier provides to MAHAR.

6. Compliance

Supplier will comply with MAHAR's specifications, including any industry standards such as ASTM (American Society for Testing and Materials), product listings, or applicable print specifications, and any MAHAR quality program for suppliers or requirements applicable to Supplier as MAHAR may develop. MAHAR reserves the right to amend and modify its supplier quality programs at any time without prior notice.

Supplier shall furnish a Certificate of Conformance (COC) and/or a Certificate of Analysis (COA) with each product lot/shipment attesting to the conformance of the product to MAHAR's

Purchase Order, contract specifications, drawings, and acceptance requirements and/or other MAHAR product requirements, as applicable.

Supplier will conform to the applicable RoHS, REACH and conflict minerals restrictive substances as defined by United States Dodd-Frank Consumer Protection Act compliance standards and certify the products provided to MAHAR are in compliance, whether component, raw material, or finish good.

If required for end-user, per Medical Device Regulation (Regulation (EU) 2017/746), Supplier will comply with Restricted Materials/Substances that are part of the Candidate list of Substance of Very High Concern (SVHC, REACH, Article 59 (10)). This restriction also applies to all carcinogenic, mutagenic and/or reprotoxic (CMR) of category 1.A and 1.B, and endocrine disruptors (ED) substances with serious effects to human health.

If required for end-user, Supplier will comply with the applicable Medical Devices Regulation (Regulation (EU) 2017/745) and certify that the products provided to MAHAR whether component, raw material, or finished goods, will integrate the requirements described in the Article 10.4 of the MDR (Medical Device Regulation) (Annex 1, General Safety and Performance Requirements).

If required for end-user, Supplier agrees to process Products in compliance with the EU Directive 722-2012 Animal Tissue used in the manufacture of medical devices or use of material of animal origin.

Supplier agrees to comply with FDA regulation 21CFR801.437; Subpart H--Special Requirements for Specific Devices, Section 801.437 User labeling for devices that contain natural rubber. This section applies to all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

Suppliers will be required to submit Safety Data Sheets (SDS) for all items supplied to MAHAR that are regulated and have safety requirements.

7. Product Non-Conformance

a. Nonconformance Determination

Nonconformity is defined as the nonconformance of PPAP or production approved products to one or more of the following documented requirements:

- Print dimensions.

- Material Specifications.
- Engineering Specification.
- Packaging Specifications.
- Mixed/wrong parts within a shipment.
- Improper identification of parts.
- Failure of a part to perform during the warranty period Mahar has extended to their end customers due to a supplier created discrepancy.

Supplier shall be responsible for any and all damages or costs incurred by MAHAR and/or MAHAR's customers as a result of Supplier's supply of non-conforming products, including a reasonable administration fee. All actual charges will be documented.

b. Supplier Notification of Nonconformance

Supplier will implement and maintain a system to quarantine and report to MAHAR any nonconforming products, including any issues that may compromise the safety of others or diminish the quality of the product thereby warranting stop shipments of the product or requiring a product recall.

- If Supplier becomes aware of any product complaints or adverse reactions that impact the products and/or services Supplier provides to MAHAR, Supplier must notify MAHAR at 1-800-456-2427 or submit the complaint electronically to MAHAR at supplychain@gomahar.com.
- Supplier, if requested by MAHAR, will conduct internal investigations, record reviews, and sample evaluations as required to determine the validity of the complaint. The findings from the investigation shall be reported to MAHAR immediately.
- If MAHAR is required or voluntarily decides to recall, withdraw, or investigate a product implicating Supplier's processes as a potential root cause, Supplier will fully cooperate with MAHAR in connection with such a recall or withdrawal.

8. Supplier Corrective Action

If MAHAR notifies Supplier of any deficiencies in Supplier's Quality Management System, product, or service, Supplier will provide documented corrective and preventive action(s) to prevent future deviations from the specification or other requirements.

- Upon MAHAR’s request, Supplier will provide MAHAR’s quality team the established corrective action document and all supporting documents pertaining to the specific problem/defect description, containment actions performed, and initial investigation performed. All documentation and actions performed will be provided to MAHAR immediately.
- Supplier will provide MAHAR the root cause analysis, and corrective/preventive action(s) taken to minimize any risk to MAHAR’s customers or end users.

9. Change Notification

The Supplier will immediately provide written notification to MAHAR of any requested changes referenced below by emailing supplychain@gomahar.com. This notification is necessary so that MAHAR may evaluate the impact of the change to the quality of the finished product and/or service provided to MAHAR’s customers.

- The following changes require advance notification to MAHAR, which may or may not be approved. This list is not all-inclusive:

<i>Change Type</i>	<i>Scope/Details</i>
Change in Production Facility	Any time an existing product is being transferred from Site “X” to Site “Y.”
Subcontractor Change	Any time a product, process, or service is moved from in-house to a subcontractor.
Equipment Change	Any change in equipment used in the manufacturing process. Any movement or relocation of equipment within the same facility; Any movement of equipment to a different facility.
Inspection Requirements	Changes to quality management process and inspection methodology, including sampling size, methods, or frequency.
Manufacturing Process Change	Any changes to the manufacturing process, including any re-sequencing or addition/deletion of a job step.
Packaging Process Changes	Any changes in packaging materials that contact.
Design Changes	Changes affecting supplier processes.
Testing (Raw material or finished products)	Changes to any testing conducted that will affect any certification provided to MAHAR.

	Any changes to testing providers.
Raw Material Change	Any change to a raw material formulation or property not defined by a design specification (e.g., colorant changes, changes of composition, etc.)
Other Substitutions	Any substitution of product.
Rework	Any product rework that does not go through the standard/original defined process (e.g., non-standard rework).
Product Discontinued	Any time an existing product has been discontinued or obsoleted.

- Supplier must provide a minimum of 120-day written notice to ensure MAHAR may complete an appropriate review of the change, including any regulatory evaluations.
- Supplier changes must be approved by MAHAR before Supplier can implement the change.
- Any impact to open purchase orders which are due to the change will be communicated to MAHAR's sourcing team at supplychain@gomahar.com to assess the impact on deliveries to MAHAR.
- Supplier will notify MAHAR of changes in the supplier's management structure via written correspondence, which may be in the form of a letter or electronic means. Such changes include but are not limited to, changes in management with executive responsibility or changes in management responsible for regulatory, quality or quality systems.
- Supplier will be responsible for the costs of any testing required by MAHAR or MAHAR's customers to validate the change/deviation. Any testing costs related to Supplier's change/deviation request incurred by MAHAR and/or MAHAR's customer will be communicated to Supplier.

10. Production/Process Controls

Supplier will ensure that all processes that directly affect the quality of products and/or rendered services, are clearly defined, and conforming to MAHAR's purchasing/processing

specification requirements applicable to MAHAR. Supplier's process controls must include but not limited to:

- Documented procedures defining the way processes are to be performed and measured.
- Use of suitable equipment and environment to produce products or services.
- Monitoring and controlling critical process parameters and product characteristics using in-process inspection and where appropriate, supporting with statistical methods. The evaluation of the produced products/rendered services shall be performed per MAHAR established critical to quality (CTQ) dimensional requirements as signified through patient risk criticality.
- Supplier shall be required to demonstrate risk mitigation of process risk per ISO 14971 (i.e. PFMEA (Process Failure Mode Effect Analysis) or relevant risk management tools).
- Documented changes to production and process controls.
- Trained qualified personnel to perform operations on MAHAR products and/or executed services. For example, where certifications are required (i.e., Fluorescent Penetrant Inspection (FPI), X-Ray, welding, etc.) only certified operators are to perform these operations.
- Defined and controlled criteria for workmanship standards.
- System(s) to protect Mahar's products from contamination by unapproved foreign materials.

11.Process Validation

Supplier's processes or outsourced sub-processes that cannot be fully verified by subsequent inspection or test methods (e.g., welding, brazing, heat treating passivation, or anodizing), the supplier and their sub-tier supplier(s) will have an established validation process that meets the needs of the specified quality system, and will minimally consist of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) and 21 CFR Part 11 compliance when applicable. Supplier's validation process will include:

- Appropriate statistical rationale for sampling strategy.
- Definition of equipment and process parameter requirements of validation IQ/OQ/PQ.

- A post-validation monitoring and control process defined by the supplier and agreed upon by MAHAR.
- A process for evaluating changes against the current validated state of the process and a method detailing revalidation activities when required.
- Supplier agrees to notify MAHAR immediately if any validation process deviations occur. The supplier will evaluate and analyze the deviation where appropriate and provide the results to MAHAR for consideration for acceptance.
- A method, if requested, to provide validation protocols and results of pre-validation process development activities including any changes to processes or equipment for which the validation requirements have been established and mutually agreed upon.

12. Shipment and Packaging Requirements

Supplier will, as deemed appropriate by MAHAR, implement, and follow packaging and shipping methods necessary to prevent cosmetic, mechanical, and electrical damages to the products shipped, as applicable. Supplier will package the product as specified on the part drawing. If no packaging is specified on the part drawing, Supplier will package the product to prevent damage or deterioration of the product and labels during shipment per MAHAR specified requirements.

13. Product Registration

Upon MAHAR's request, Supplier will submit all non-proprietary information needed for registration of the product. Supplier will ensure that MAHAR is involved in any changes, which may affect the product's regulatory status. Supplier will make available proprietary information to regulatory agencies through a master file or equivalent document in the English language.

Revision History

<i>Rev</i>	<i>Date</i>	<i>Section Modified/Description of Change</i>
0	2/28/24	New Document