



ISO 13485 Contract Manufacturing Survey and Profile Response

Hisco shares your commitment to legal and ethical business practices, and we offer this document to satisfy the need for pertinent information regarding our business profile, practices, and organizational attributes. We hope this response provides the assurance that Hisco is committed to uncompromising integrity in its business practices.

His Company Inc. dba Hisco, Inc.
Executive Office: 6650 Concord Park Dr.
Houston, TX 7704
Website: www.hisco.com

Founded/Incorporated: 1971
State of Incorporation: Texas
Company Type: Corporation
Classification: Large Business

Company Overview: Hisco is a specialty distribution company with numerous stocking locations serving the electronic assembly, aerospace and defense, medical, and other industrial markets throughout North America, including subsidiaries HiscoMex in Mexico and HiscoCan in Canada. Hisco's contract manufacturing divisions, DBA Precision Converting provides value-added custom-fabricated and converted parts in an FDA registered and ISO 13485 certified facility. For company history and additional information please refer to the Hisco About-Us website at [About Us \(hisco.com\)](http://About Us (hisco.com)).

Our Mission: We are committed to our role as a trusted solutions provider with profitable growth through investment, innovation, and operational excellence.

Employment Policies: Hisco provides equal employment opportunities without regard to race, color, sex, religion, national origin, age, veteran status, or disability. Hisco conforms to all applicable federal and state laws, rules, guidelines, and regulations, and provides equal employment opportunities in all employment and employee relations. For additional information on EOE or other employment practices, please visit our Hisco Careers website at [Careers \(hisco.com\)](http://Careers (hisco.com)).

W9 Requests: You may request a W9 form through contacting a Customer Service at customerexperience@hiscoinc.com or Sales representative. Please include your company name and location in your email request.

Confidentiality and Non-Disclosure Agreements: Hisco routinely works with customers where specific content shared between parties must occur in a confidential manner. Hisco limits the involved parties to only those necessary for specific functions and as mutually agreed upon with the customer. If confidential information has been determined necessary to pass between parties, a non-disclosure agreement may be considered and would be negotiated at that time in a manner that is clearly defined and specific to the nature of the business relationship. You may request a confidentiality or non-disclosure agreement by submitting an email to Legal@Hiscoinc.com. Please include your company name, location and identify the recipient's legal entity information in your email request.

Terms and Conditions: Hisco's customer, supplier/vendor, privacy, cyber security, conflict minerals, quality and other policies are available on the Hisco Policy website at [Legal \(hisco.com\)](http://Legal (hisco.com)). Please contact a Customer Service or Sales representative for ordering, lead times, prices, fees, payment terms, and payments.

ITAR Registered: Hisco, Inc. is listed with the United States Department of Defense as an ITAR-registered supplier. This allows us to produce products and OEM assemblies for customers that require ITAR regulation management and control. Additional information and our ITAR Registration Letter is available on the Hisco website at [ITAR Registered \(hisco.com\)](http://ITAR Registered (hisco.com)).

Quality Policy: We strive to provide the highest possible level of product quality and customer satisfaction through the understanding of our customers goals, expectation, and requirements. We will accomplish this by defining, strictly following, and continuously improving a Quality Management System that complies with all applicable customer and regulatory requirements.

Quality Management System and Certificates: Our FDA registered (registration number: 3009843176) contract manufacturing site follows a Quality Management System certified with ISO 13485 standards and compliant to 21 CFR 820 regulations. The contract manufacturing facility and its practices are regularly audited to the applicable requirements.



Current ISO certificates are available on the Hisco Quality website at [Quality \(hisco.com\)](https://www.hisco.com/Quality) and Precision Converting website at [Quality Commitment \(precisionconverting.com\)](https://www.precisionconverting.com/QualityCommitment).

Compliance and Safety Data Sheets: Product compliance documents such as RoHS, Reach, Cal. Prop 65, etc. relative to specific products are available upon request through Compliance@hiscoinc.com.

Quality Management System Elements

Administrative Elements

- Hisco's contract manufacturing site follows a documented Quality Management System (QMS) certified to ISO 13485 standards and compliant to 21 CFR 820 regulations. The QMS Manual (document CM-ISO13485) is available to customers upon request at MfgQuality@Hiscoinc.com. Please include your company name, location and identify the Hisco site you are doing business with within your email request.
- Certificates for certified sites can be found on our website, [Quality \(hisco.com\)](https://www.hisco.com/Quality).
- Organization charts are employed to identify the reporting structure, authority, and identification of Management Representatives.
- Hisco has defined, documented, and periodically reviews policies, procedures, and work instructions as required within the management system to ensure compliance with business practices, customer requirements, and standards. This information is considered proprietary and is not disseminated publicly. However, this information may be viewed during an audit.
- Employees are routinely trained in policies and procedures. Training records are maintained and retained based on corporate documentation retention policies.
- QMS assessments to ensure effectiveness are conducted through scheduled internal audits, management reviews and on-going evaluations of metrics to quality objectives. Leadership is committed to continual improvement of the organization and the QMS to ensure customer satisfaction.

Documentation

- Hisco has controls in place to ensure only the latest documents are available for access by personnel.
- Obsolete documents and Quality records are indexed and stored for timely retrieval.
- Batch history records are stored as part of the overall batch record for a Lot of manufactured products and retained in accordance with retention policies.
- Hisco has a record retention policy that is consistent with industry standards. When applicable, customers may take possession of the product records at their expense at the end of Hisco's retention period if their retention requirements are longer. The general retention period is 10 years from date of record creation.

Change Control

- Hisco employs change control practices for its products and services. Hisco requires suppliers to provide notification if the supplier plans to make changes in product and/or process, changes of suppliers, changes of manufacturing facility location.
- Hisco will provide notification to all impacted customers of the pending changes upon becoming aware of the change from a supplier.
- Contract manufacturing facilities ensure change control processes are employed, where required for internal changes. Hisco will carry out change control activities compliant to ISO 13485 activities to communicate to customers, verify or validate the change, where required. Examples, where change control would be utilized, include changes to the material source of supply, manufacturing processes, site, formulation, specification, test methods, and critical equipment.
- Deviation practices are employed to obtain customer approvals for planned changes from the approved process for an interim period.



Supplier Controls

- Hisco has established the requirements and controls required to be applied to externally provided products, and services. Suppliers on our Approved Supplier's List (ASL) are monitored and evaluated to ensure compliance with the elements outlined in our program.
- Hisco routinely works with OEM suppliers to source and identify materials to meet customer's functional requirements and needs.
- Product requirements and controls are employed to direct and sub-tier providers are appropriate to the risk, and in accordance with customer requirements.

Customer Service & Ordering

- Contract Review of incoming order requirements prior to order acceptance are conducted to ensure all customer requirements are clearly identified and achievable.
- Hisco's Customer Service and Sales will work with customers when contract changes are required. This may include changing orders, specifications, change control, supplier standards, and/or Quality Agreements.
- Instructions specific to customer requirements are clearly defined, flowed down, and communicated throughout the supply chain to ensure all requirements are understood and can be met.

Receiving Inspection

- Incoming receiving requirements for materials are subject to receiving inspection standards, including practices to prevent counterfeit materials.
- Material certification and inspection records are kept on file subject to the record retention policy outlined in the documentation section.
- Controls are in place that prevent nonconforming material from being put into stock or inadvertently distributed. Material is electronically and systematically controlled and monitored within the facility.

Process Controls

- Written instructions are in place for personnel performing specific processes to ensure the output meets requirements for the provision of our products and services.
- Processes are in place to ensure the environment does not have an adverse effect on product quality, such as: the health, cleanliness of the personnel and facility, line clearance practices, material flow practices and tagging system, and contamination controls.
- Documented information is maintained to establish that the processes have been carried out as planned and that demonstrate the conformity of our products and services.
- Batch processes are monitored and recorded at the end of each critical production step generally utilizing process router/traveler systems to monitor the status of the jobs.

Equipment Control

- Hisco tracks, calibrates, and verifies critical inspection, measurement, and test equipment traceable to NIST or another suitable standard when required in accordance with defined frequencies.
- Equipment critical to the processes at Hisco is tracked and maintained based on defined frequencies to ensure the performance of the equipment.

Inspection Process

- Inspection points are strategically placed and performed throughout the manufacturing process after critical process steps, or in accordance with customer requirements.
- Inspection based on a statistically valid sampling plan or in accordance with customer requirements.
- Inspection records are kept on file subject to the record retention policy outlined above.
- Controls are in place that prevent uninspected/unreleased material from being shipped. Material is electronically and systematically controlled and monitored within the facility.
- Certificate of Conformance is provided with every shipment. A Certificate of Analysis may be available upon request.



Handling, Storage, Preservation & Delivery

- Hisco ensures materials and products are identifiable and traceable throughout the supply chain process. Materials are traceable to certifications, purchase orders, production orders, and sales orders.
- Hisco ensures materials and products are stored and handled in a manner that precludes damage and deterioration where required. In addition to storage precautions, packaging practices for reasonable protection from damage and deterioration are utilized.
- Procedures are in place to ensure that different customer orders are not commingled. Same customer orders may be consolidated for shipment where necessary.
- All critical products are identified throughout the handling process, including batch/lot information and storage requirements.
- Materials that have a limited shelf life are tracked per Lot control where required. Product is identified with labels that note the expiration date.
- The facility has established housekeeping practices to ensure adequate control of the work environment, including but not limited to temperature and humidity monitoring, pest control policies and cleaning programs.

Packaging & Labeling

- Hisco has documented packaging controls, instructions, and standards in place dependent upon product type or customer specific requirements.
- A customer's packaging and labeling requirements are generally defined during the contract manufacturing quoting process. Where specific packaging or labeling is required, contact Hisco Sales to ensure that requirements are defined prior to ordering.
- Label reconciliation practices are employed, where applicable.

Nonconforming Control

- Physical and electronic controls are in place to monitor, handle and control nonconforming materials.
- Nonconforming material including suspected counterfeit materials, is identified, and segregated to preclude inadvertent use. The product is quarantined and cannot be moved until disposition. When applicable, engaging the customer's approval may be part of the disposition process.
- Materials that are dispositioned for "rework" are re-inspected after rework has been performed as defined in the rework procedure, engaging the customer's approval may be part of the rework process.

Corrective/Preventative Action and Improvements

- A Corrective Action and Preventive Action process that is compliant with appropriate regulations and procedures is employed.
- Root Cause Analysis is performed as a component of the Corrective Action process. Preventive actions are employed with the Corrective Action process, where applicable.
- Improvements to the management system are made through the Prevention Action process.

Customer Satisfaction

- Feedback from customers is documented and evaluated to ensure that customers' expectations are met.
- Evaluation and actions are taken when necessary to remediate issues.

Any Quality Process or Fabrication information not found in this document or on the Hisco websites such as scrap rate, rework rate, manufacturing routings, plant shutdowns, plant capacity, delivery history, etc. is proprietary and will not be publicly disclosed.

For additional information and questions please contact MfgQuality@hiscoinc.com.