Your Trusted Technology Partner

VIRTEX

Quality Manual

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Table of Contents

Note: The Table of Contents aligns with the ISO 13485:2016 structure. The clauses for ISO 9001:2015 and AS9100D are in noted in ( ) for reference.

Commitment to Quality

In order for Virtex to successfully compete and grow in contract manufacturing of complete turnkey electronic and electro-mechanical assemblies and products, it is essential that we consistently meet or exceed our customer's requirements and expectations in order to enhance customer satisfaction. Virtex accomplishes customer satisfaction by Management Review meetings which include Top Management that determine external and internal issues that are relevant to its purpose and its strategic direction and its ability to achieve the intended results of our QMS.

Virtex is committed to learning and understanding our customer's needs and expectations, and to developing a flexible customer partnership that results in mutual benefits to us, our customers, and the end-users of the products manufactured at Virtex

Virtex is committed to success and growth through continuous improvement involving the latest technology, knowledgeable and experienced resources, and an outstanding reputation for meeting industry standards in Medical, Aviation, Space, Defense, Computer, Industrial, Communications, and more. Virtex's goal for commitment to quality is defined in policies in our Quality Manual in our Quality Policy:

"Virtex is a service oriented, quality driven contract manufacturer committed to complying with customer, applicable statutory and regulatory requirements, and applicable quality management system requirements, and to maintaining the effectiveness of the quality management system. Virtex is dedicated to customer satisfaction and growth, through continual quality improvement and employee involvement."

1 Scope and Introduction (4.2, 4.3)

Virtex has supplied high quality cost effective customized electronic solutions since 1974. Virtex is a small business providing the sale of electronic and electro-mechanical assembly and sub-assembly manufacturing and test services to a wide variety of markets and industries including: Medical, Aviation, Space, Defense, Computer, Industrial, Communications, and more. Virtex has a 65,000 sq. ft. environmentally controlled facility located in Anoka, a northern suburb of Minneapolis, MN. This facility employs approximately 105 people with an average tenure of over ten years. Major systems and processes have been installed and implemented to ensure this facility is environmentally friendly. This includes complete lead-free processing for RoHS compliance and environmental safety.

Virtex's sale of contract manufacturing services range from prototypes too low to medium volume production. Virtex's customers can select from a variety of services that includes consignment, turnkey, or a combination of each, both rigid and flexible PC board assembly, complete box build, test, order fulfillment and servicing. The company's capabilities are supported by eight surface mount lines. All lines are complete stand-alone systems with

magazine feeds, conveyerized drives and automatic optical inspection (AOI) to provide fully automated assembly. Virtex also provides manual through-hole assembly processes with conveyerized assembly lines, in-line wave solder and aqueous /semi-aqueous in-line cleaning systems for both leaded and lead free assemblies. Virtex offers in-circuit (ICT), Flying Probe and functional testing utilizing all the major ICT test platforms. Facilities for burn-in, environmental and thermal cycle testing, cable and harness assembly, and automated and manual masking/epoxy and conformal coating systems are all provided on site.

Virtex has implemented an FDA/cGMP, ISO 13485: 2016, ISO 9001:2015 and AS9100D compliant Quality Management System to ensure and enhance all customers' quality needs and expectations are obtained, understood, implemented and often surpassed. Virtex's emphasis on meeting our customer's product requirements includes those applicable regulatory and statutory requirements for the quality management system and those related to safety and performance of a medical device. If there is a conflict between the requirements of these standards and the customer or applicable statutory or regulatory requirements, the latter shall take precedence.

This quality manual applies to the QMS at the facility located in Anoka Minnesota, and describes the policies procedures and requirements implemented by Virtex to ensure customer satisfaction, to support continuous improvement efforts by applying a risk based approach to the control of the appropriate processes of the quality management system and to accomplish our goal as stated in the scope. Virtex's Top Management has determined the interested parties that are relevant to our quality management system to be our customers, suppliers, employees and regulatory (FDA) and product safety agencies. Virtex Top Management monitors and reviews customer and supplier performance along with customer statutory and regulatory requirements during scheduled management review meetings. Virtex is committed to developing mutually beneficial working partnerships with our customers.

Some activities addressed by ISO 13485:2016, ISO 9001:2015 and AS9100D are outside the scope of work performed by Virtex. These activities are addressed as permissible exclusions in 4.2.2.

Virtex provides the sale of electronic and electro-mechanical assembly and sub-assembly manufacturing and test services to a wide variety of markets and industries including: Medical, Aviation, Space, Defense, Computer, Industrial, Communications, and more. Virtex also provides material turn-key services, although consignment of material from the customer is also an option. Virtex has determined the scope of the quality management system to include the sale of electronic and electron-mechanical assembly and sub-assembly manufacturing, inspection, test and shipping. Virtex takes a customer's design along with Drawings, Bill of Materials, test specifications and manufactures/tests to customer specification. Virtex ships product to the customer as the customer specifies.

2 Normative Reference

Virtex's Quality System has been developed and implemented to meet our customers' requirements and the ISO 13485:2016, ISO 9001:2015, and AS9100D Standards. The

following documents were used during the development and implementation of our quality system:

- American National Standard ANSI/ISO/ASQ Q9001:2015, Quality Management Systems - Requirements.
- FDA/cGMP Quality System Regulation (QSR) 21 CFR 820.
- ISO 13485:2016
- ISO 14971, Medical Devices-Application of risk management to medical devices
- SAE Aerospace Standard AS9100D.
- ISO 9000:2015 Quality Management Systems- fundamentals and vocabulary.
- ISO 10007 – Quality Management Systems-Guidelines for Configuration Management.

3 Term and Definitions

The Terms and Definitions listed in ISO 13485:2016, 9001:2015 and AS9100D apply to Virtex's Quality Management System. The following list of Terms not covered in ISO 13485:2016, 9001:2015 and AS9100D are provided for clarification of Virtex's usage. Specific terms listed in AS9100D are listed below for immediate reference.

Consigned Material - Any customer supplied product, raw material or assemblies to be utilized in the manufacture of the product supplied to the customer.

Turnkey/Purchased Product - All material/product purchased by Virtex for a customer, required to accomplish completion of a customer's order. Material/Product is provided by a party outside the organization's quality management system.

Customer Owned Property - Any customer owned property such as tooling, fixtures, instrumentation, accessories, and documentation supplied or paid for by the customer, specific to the customer's product.

Request for Quote (RFQ) - A document from a potential or existing customer defining the requirements of the product for which they are requesting we provide our expertise and service.

Quote - A document generated by Virtex for a potential or existing customer defining the services to be provided.

Program Manager - defines the primary contact at Virtex to the customer, who is responsible for ensuring customer requirements and specifications are understood and communicated internally to those functions responsible for carrying out customer requirements.

Job - confirmation of a customer order signifies creation of a job. A job is created for each purchase order received. Each job is assigned an Virtex job number which identifies the product through all activities at Virtex. The job number allows reporting of all activities, including those who perform such activities, to the specific job.

Job Folder - a folder specific to the customer's purchase order, identified with an Virtex job number, which is created upon acceptance of the purchase order. The job folder holds

all job-related information and documentation necessary to complete the customer's order. All documentation required in the job folder is a result of quality planning and product realization.

Job Traveler – a folder specific document listing the operations/processes the job will require. Specific job instructions are documented under the operation/process applicable.

Device Master Record - the master file, also known as a medical device file, by customer which includes a general description of the medical device and its intended use/purpose, customer assembly number, which includes a compilation of data containing specifications and procedures specific to the product or where to find them. This file includes a customer controlled Bill of Material, Drawing, approved vendors by part number, software specifications, and supplied product specific work instructions, including labelling. The file also includes, Virtex's job routing with all Virtex generated notes pertaining to the assembly, production process specifications, methods, standard operating procedures including environment specifications as appropriate, quality requirements and equipment required, and all packaging and labeling requirements including methods and processes used.

Customer Order - An Virtex generated order number used for tracking of customer purchase orders, shipping, and invoicing.

Design for Manufacturability/Testability Critiques - critiques provided free of charge to customers relating to board fabrication and layout, component selection and package type, and test capabilities to assist in providing quality product utilizing the most efficient material and methods to ensure the most cost effective products.

Product- product intended for or required by a customer, or any intended output resulting from the product realization process. Product is results of a process from the following generic categories; services, software, hardware, processed materials (based on the dominant element).

Quality Records - Documentation of activities where records of such said activities must be maintained as specified in documented procedures and work instructions.

Rework - The act of repeating one or more manufacturing operations or performing alternative techniques in order to bring product into compliance with applicable drawings and specifications.

Repairs- The act of restoring the functional characteristics of a defective product without necessarily restoring the appearance of compliance with applicable drawings or specifications.

Risk – Combination of the probability of occurrence of harm and severity of that harm. An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

Risk Management – systematic application of management policies and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.

Special Requirements – Those requirements identified by the customer or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special

requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

Critical Items – those items having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

Key Characteristics – An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.

Configuration Management - Coordinated activities to direct and control configuration. Configuration Management generally concentrates on technical and organizational activities that establish and maintain control of a product and its product configuration information. The product configuration information is the requirements for product design, realization, verification, operation and support.

Medical Device – instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacture to be used, alone or in combination, for human beings.

Counterfeit Part – an unauthorized copy, imitation, substitute, or modified part which knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

Product Safety – The state in which a product is able to perform to its designated or intended purpose without causing unacceptable risk of harm to persons or damage to property.

4 Quality Management System/Context of the Organization (4)

4.1 General Requirements

Virtex has established, maintains and strives to continually improve a Quality Management System (QMS) in order to ensure that products consistently meet customer and applicable statutory and regulatory requirements, and to maintain a competitive edge in the industry. This manual describes Virtex's policies for quality, continual improvement, and customer satisfaction.

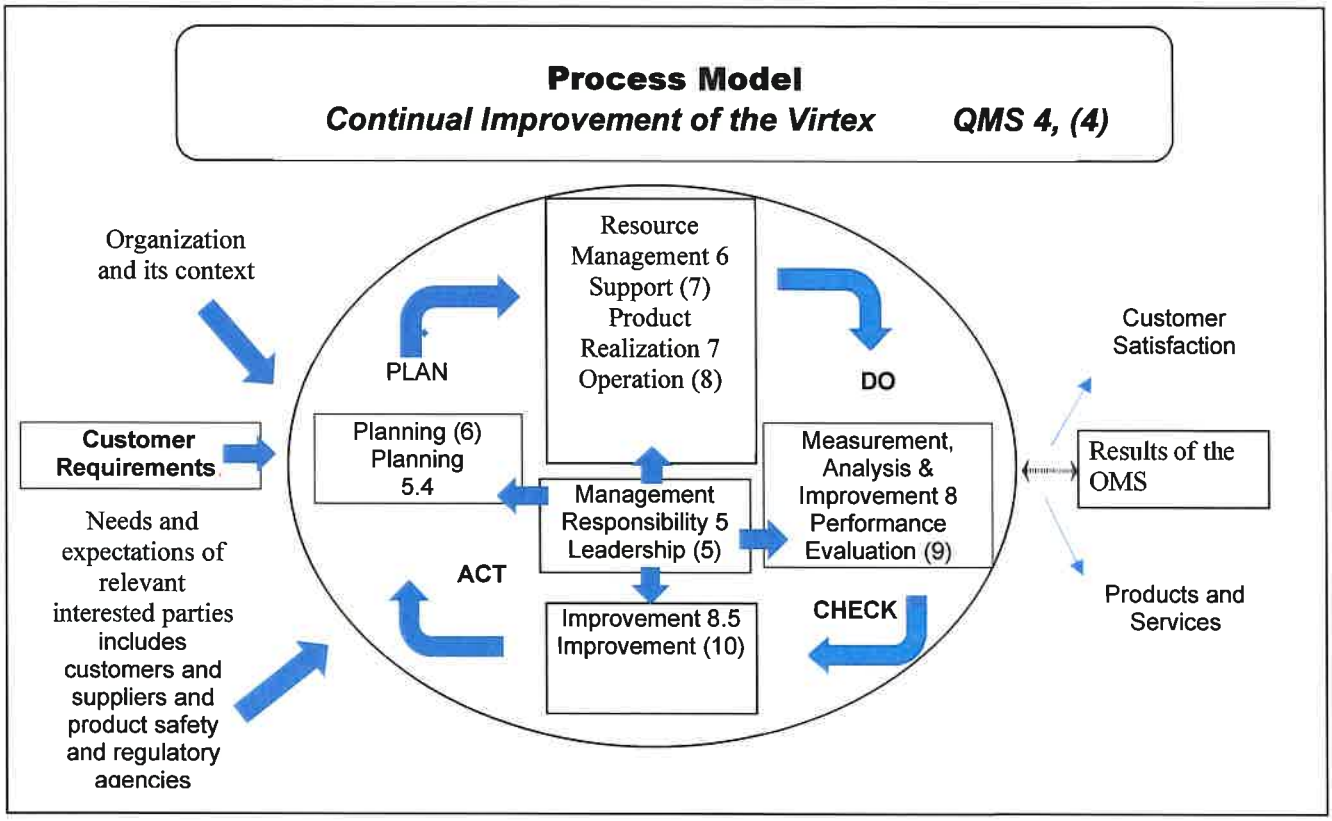

Figure 1: Process Model of the Virtex Quality Management System
Note: Virtex has identified the ISO 13485:2016 clauses, the ISO 9001:2015 & AS9100D are in ( ).

The process model shown in Figure 1 provides an overview of Virtex's continual improvement process. The model demonstrates the linkages between the processes defined in this manual. "Plan-Do-Check-Act" improvement methodology is applied to these processes, in support of Virtex's quality goals and objectives. Virtex's quality management system uses risk-based thinking for achieving an effective quality management system by addressing both risks and opportunities to achieve improved results and prevent negative effects. Virtex's QMS also addresses customer and applicable statutory and regulatory QMS requirements. Virtex's Top Management determines the processes needed for the QMS and their application throughout the organization. A sequence of these processes and interactions is shown in Figure 2. For the processes shown in figure 2, key details such as inputs and outputs, criteria, and methods and measurements are defined within documented procedures and other documented methods.

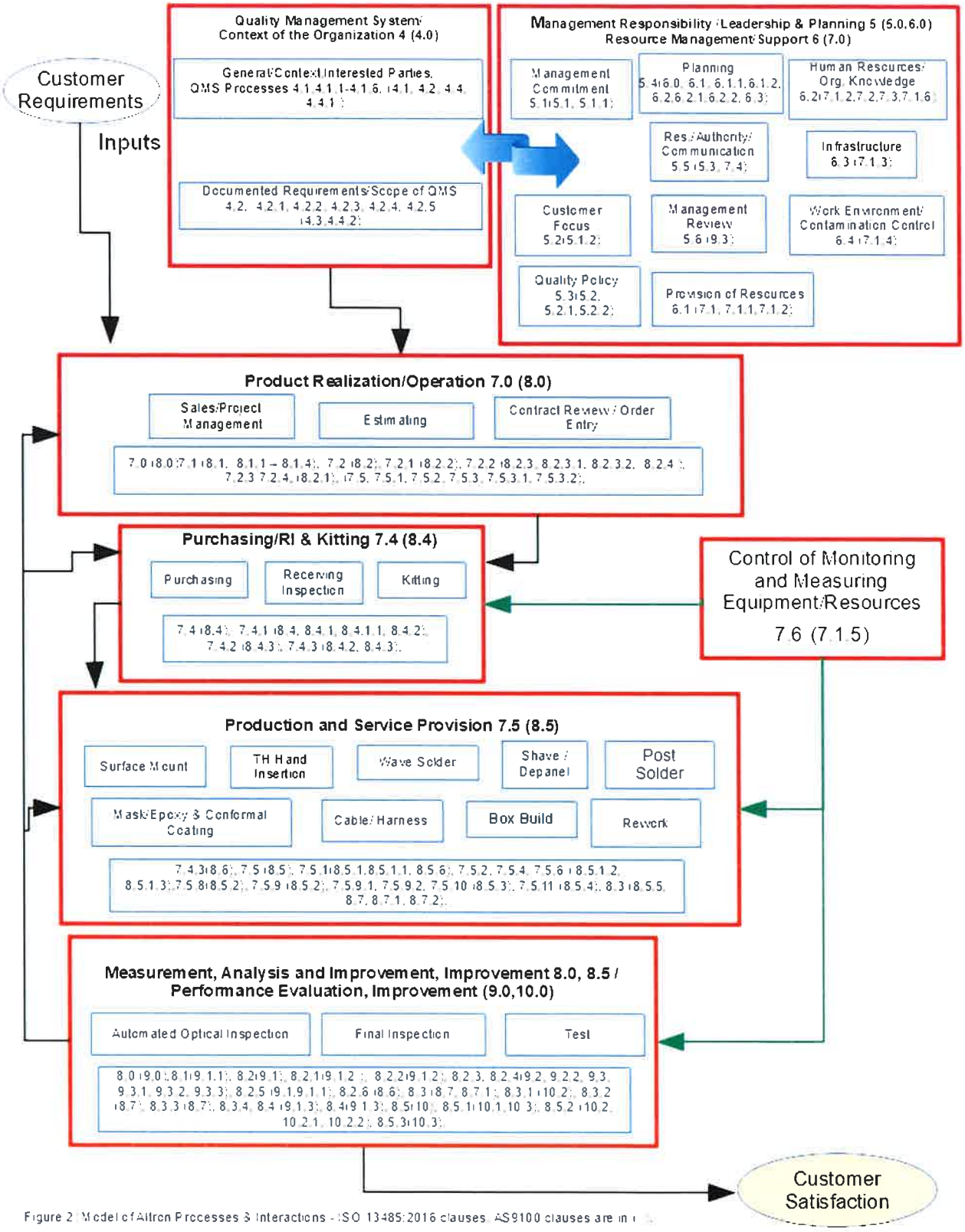

Figure 2 : Model of Altron Processes & Interactions - ISO 13485:2016 clauses, AS9100 clauses are in ( ).

Figure 2: Model of the Virtex Processes and Interactions

Note: Virtex has identified the ISO 13485:2016 clauses, the ISO 9001:2015 & AS9100D are in ( ).

These models do not show the individual processes in detail. The details regarding how Quality Management System requirements are met are provided in procedures, work instructions, and other documents. These requirements flow down to external providers when outsourcing processes that affect product conformity. Controls of the external providers are proportionate to the risks involved and the ability of the external provider to meet requirements,and include written quality agreements. These, along with customer supplied documents, are controlled and are available to employees in order to ensure the continued effective implementation of the system, including availability of resources and compliance with customer, ISO 13485:2016, ISO 9001:2015, AS9100D, FDA/cGMP and applicable statutory and regulatory requirements. These documents also describe how various processes of the quality system, including computer software used in the QMS, are identified, determined, defined, controlled, verified, measured, monitored, analyzed, and validated for the QMS to accomplish desired goals and objectives, and to ensure the effective functioning and administration of the quality system.

4.2 Documentation Requirements

Document, Form and Electronic Data Control Procedure - 1010000

4.2.1 General

Virtex's Quality Management System documentation, along with this Quality Manual, includes a documented Quality Policy and our quality objectives, controlled documented procedures, work instructions, quality records and documents required for effective planning, operation, control, and monitoring of processes. Personnel, including customer, and/or regulatory authorities, have access to and are aware of relevant quality management system documentation and changes.

A Device Master Record and Device History Records are maintained. The Device Master Record may be in the form of binders containing the relevant documents or in the form of an index listing the relevant documents and their locations.

Virtex procedures linking to the ISO 13485:2016, ISO 9001:2015 and AS9100D standards are noted in each applicable section of the Quality Manual.

4.2.2 Quality Manual

Quality Management System - 7010029

Virtex's Quality Manual was established to describe our organization's quality management system. The scope and permissible exclusions of the Quality Management System are described in section one of this manual. The quality manual references documented procedures established for the quality management system and a description of the interaction between processes of the quality management system. See Figure 2.

Some activities addressed by ISO 13485:2016, ISO 9001:2015 and AS9100D are outside the scope of work performed by Virtex. These activities are addressed as permissible exclusions below.

Virtex provides the sale of electronic and electro-mechanical assembly and sub-assembly manufacturing and test services to a wide variety of markets and industries including: Medical, Aviation, Space, Defense, Computer, Industrial, Communications, and more. Virtex also provides material turn-key services, although consignment of material from the customer is also an option. Virtex has determined the scope of the quality management system to include the sale of electronic and electron-mechanical assembly and sub-assembly manufacturing, inspection, test and shipping. Virtex takes a customer's design along with Drawings, Bill of Materials, test specifications and manufactures/tests to customer specification. Virtex ships product to the customer as the customer specifies.

Virtex has determined that the following sections are not applicable due to the nature of our organization and the services provided. Virtex does not design and develop product, and does not do installation activities. Virtex does not have the facilities to perform manufacturing of finished sterile medical devices, therefore implantable devices. This exclusion does not affect Virtex's ability or responsibility to provide products that meet customer, medical, regulatory, statutory or aviation, space, or defense industries requirements.

- Design and Development (Clauses 7.3 ISO 13485:2016, 8.3 AS9100D/ISO 9001:2015)
- Installation Activities (Clause 7.5.3 ISO 13485:2016)
- Sterile Medical Devices (Clauses 7.5.5, 7.5.7, 7.5.9.2 ISO 13485:2016)

4.2.3 ***Medical Device File*** Document, Form and Electronic Data Control Procedure -1010000

For all medical devices, Virtex establishes one of more files containing or referencing documents received/generated to conform to requirements. Virtex refers to this as the Device Master Record (DMR) Each medical device type or family includes a general description, intended use/purpose, labelling requirements, including any instructions for use, product specifications, procedures for manufacturing, packaging, storage, handling and distribution as applicable, measuring and monitoring and servicing as applicable.

4.2.4 Control of Documents Document, Form and Electronic Data Control Procedure - 1010000

All documents/documented information which are part of the QMS are controlled according to the Document and Data Control Procedure. This procedure defines the process for:

- the controller of a procedure and approval process for ensuring adequacy prior to use;
- reviews and updates as necessary, including re-approval of documents;
- identifying changes to a document and identification of current revision;
- control of the Master Log of controlled documents to ensure applicable documents are available at the point of use;
- ensuring all controlled documents are legible and readily identifiable;
- external data and job folder information is controlled, identified and maintained per the Device Master Record. The Device Master Record shall also contain: product specifications, and procedures for manufacturing, and defines controls to prevent

deterioration or loss. Job folder information requires a red folder stamp per Job Folder Creation #1010008; and

- maintenance of at least one copy of each obsolete revision of a controlled document is maintained in a history file.

4.2.5 Control of Records

Control of Quality Records Procedure -7010031

Quality records are maintained in accordance with the Control of Quality Records Procedure, which defines retentions times including specific retention times per customer requirements, along with the controls necessary for identification, storage, protection, security and integrity, retrieval and disposition of records. These Quality records include our internal records as well as supplier records. Quality records provide evidence of conformity to customer requirements and to Virtex's QMS and include records created by and/or retained by suppliers.

Records related to medical devices are maintained permanently or for at least equivalent to the life time of the product, as defined by the customer.

Records are available for review by customers and regulatory authorities in accordance with contract, regulatory and statutory requirements.

5 Management Responsibility/Leadership (5)

5.1 Management Commitment

Management Responsibility/Leadership - 7010028

Virtex's top management demonstrates their commitment to the quality management system by communicating the importance of meeting customer industry, statutory and regulatory requirements to employees at all levels of the organization. Commitment to communicate Virtex's commitment to quality is also demonstrated through production, sales and purchasing meetings, planning of product realization meetings, staff meetings, and periodic company meetings. These meetings provide communication and direction regarding customer requirements and attaining customer satisfaction. Among other activities related to quality issues, management ensures that a quality policy and quality objectives are established per Measurement, Analysis and Improvement #7010062, that reviews of the performance of the quality system are conducted per Management Review #7010060, which include product conformity/quality and on-time delivery performance measures, and that the required resources for the proper functioning of activities affecting quality and customer satisfaction are available. Top Management promotes the use of the process approach and risk-based thinking. Top management assures appropriate actions are taken if planned results are not or will not be achieved.

Documented procedures for identification of and compliance to legal and regulatory requirements concerning the quality and functionality of products and services are established and maintained. Employees affected are made aware of the importance of meeting these requirements.

5.2 Customer Focus

Customer Satisfaction Survey-1010010

To achieve customer satisfaction, Virtex's management ensures that customer needs and expectations, including applicable statutory, regulatory or legal requirements, are understood and documented, and that these requirements are met. A Program Manager is assigned to each customer to ensure all risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed, understood, documented, and communicated to appropriate employees within our organization with the focus on enhancing customer satisfaction. In order to monitor the effectiveness of these activities, product conformity/quality, on-time delivery, and customer satisfaction/ feedback is measured. Appropriate actions are taken if planned results are not or will not be achieved is also included in management review.

5.3 Quality Policy

Top management has established the following quality policy with the involvement and understanding of our employees:

> ***Virtex Quality Policy***
>
> "Virtex is a service oriented, quality driven contract manufacturer committed to complying with customer, applicable statutory and regulatory requirements, and applicable quality management system requirements, and to maintaining the effectiveness of the quality management system. Virtex is dedicated to customer satisfaction and growth, through continual quality improvement and employee involvement."

Top management ensures that the quality policy is communicated to all employees. The quality policy is communicated to employees through training, meetings, and posting of the quality policy throughout the facility. The Quality Policy is available to customers, suppliers, employees and regulatory agencies on Virtex's website.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization.

5.4 Planning (6.0)

5.4.1 Quality Objectives

Management Review-7010060

Quality objectives are established annually to support Virtex's efforts in achieving the quality policy. The quality objectives are translated into measurable performance goals applicable to individual department processes throughout the organization. At each management review meeting, the progress of each department process towards achievement of their goals is reviewed and appropriate actions are taken.

The quality objectives are documented in Management Review meeting minutes and are communicated throughout the organization. Departmental goals are established, measured and communicated throughout the organization, as appropriate.

5.4.2 Quality Management System Planning

Quality Management System Planning - 7010061

The quality system has been planned and implemented to meet our quality objectives. Quality planning that affects the quality system includes determining the risks and opportunities that need to be addressed to give assurance the quality management system can achieve its intended results, enhance desirable effects, prevent or reduce undesired effects, and achieve improvement. These activities to address risks and opportunities are planned and documented and communicated to Top Management for approval prior to implementation. Virtex integrates and implements the actions into our QMS and evaluates the effectiveness of these actions.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Organization Chart - 1040000

Responsibilities and authorities are defined throughout the organization. The Organizational Chart is established to show the interrelation of departments and personnel within the organization.

Job descriptions define the responsibilities and authorities of all positions at Virtex Controlled procedures used throughout the organization further define responsibility and authority. Job descriptions, the organizational chart, and controlled procedures are reviewed and approved by management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

The responsibility for communicating with regulatory authorities regarding adverse events or advisory notices lies with the customer.

5.5.2 Management Representative

Management Responsibility/Leadership - 7010028

The Vice President of Quality has been appointed as Management Representative by the General Manager of Virtex and has the responsibility and authority for oversight to:

- ensure that the processes needed for the quality management system are established, implemented, and maintained;
- report to the General Manager and other management on the performance of the quality management system, and communicate needed improvements;
- promote awareness of regulatory and customer requirements throughout the organization;
- act as a liaison with external parties such as customers or auditors on matters relating to the QMS; and
- unrestricted access and organizational freedom to the General Manager and top management to resolve quality management issues.

5.5.3 Communication

Management Responsibility/Leadership-#7010028

Processes are established for communicating the effectiveness of the QMS within the organization. Methods of communicating the effectiveness of the QMS include: production meetings, sales and purchasing meetings with department heads and Top Management, project planning meetings held as required lead by the Sales/Program Manager, periodic company meetings, management review meetings, quarterly department meetings include review of QMS key process metrics at a minimum customer and supplier FPYs and On-Time delivery, individual department yields, and internal and external audit results. This communication provides employees with visibility of the effectiveness of Virtex's QMS. Virtex determines internal and external communications relevant to the quality management system in various procedures and processes throughout the organization.

5.6 Management Review

Management Review - 7010060

5.6.1 General

The General Manager, along with additional management review the QMS semi-annually at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness including the extent to which quality objectives have been met. This review identifies risks and opportunities for improvement and required changes. Records of management review meetings are maintained, including decisions made, assigned actions, and completion.

5.6.2 Review Input

QMS Process Monitoring, Measurement & Improvement-7010064

Monitoring and Measurement of Product - 7010065

Assessment of the QMS is based on a review of information inputs on the performance and effectiveness of the QMS to management review. These inputs include the following:

- audit results;
- supplier acceptance/rejection, on-time delivery and key supplier evaluation results;
- customer satisfaction and feedback, complaint handling and customer on-time delivery;
- customer process performance, based on measurements and goals; and product conformity based on customer returns, including servicing records as appropriate;
- follow-up actions from previous management reviews including nonconformities and CAPA ;
- internal and external changes that could affect the quality management system;
- applicable new or revised regulatory and statutory requirements;
- opportunities for improvement; and
- resource needs.

5.6.3 Review Output

Measurement, Analysis and Improvement - 7010062

During management review meetings, the General Manager along with additional management identifies decisions and actions to be taken regarding the following:

- progress towards achievement of the quality goals and objectives, and continuing suitability of the quality policy;
- changes required to improve the effectiveness of the quality management system and its processes;
- changes determined to be required to improve customer requirements which result in increased customer satisfaction and/or improved feedback;
- resource needs;
- applicable changes needed for new or revised regulatory and statutory requirements;
- risks and opportunities for improvement identified.

6 Resource Management/Support (7.0)

6.1 Provision of Resources

Resource Management - 7010063

Virtex's QMS is implemented and maintained through management's commitment to ensure adequate and sufficient resources are available to support the QMS and continually improve its effectiveness.

This commitment of resources allows Virtex to meet our goals to enhance customer satisfaction by meeting customer, statutory and regulatory requirements.

6.2 Human Resource

Corporate Training Program – 9010003

People, Competence, Awareness and Training - 9010001

Resource Management -7010063

To ensure competence of all personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with necessary training required, provide the competence required for each position. Qualifications for all employees are reviewed upon hire, when an employee changes positions and as the requirements for a position change. Qualifications include job descriptions, resumes, application, certifications and training checklists. Human Resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated for effectiveness. Training and evaluation are conducted according to documented training procedures. All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Virtex determines the knowledge necessary for operation of its processes and to achieve conformity of products and services. This knowledge is maintained and is made available to the extent necessary. Virtex addresses changing needs and trends and considers

its current knowledge and determines how to acquire or access any necessary additional knowledge and required updates.

6.3 Infrastructure

Facility Control Procedure - 7010036

To achieve product conformity, Virtex identifies, provides, and maintains facilities needed to meet quality objectives and product requirements. This includes building, workspace and associated utilities. We perform preventative maintenance and cleaning of manufacturing equipment, and records of maintenance are retained. Supporting services, such as our computer system, are in place to ensure efficient process flow and accuracy to meet customer requirements. As new infrastructure requirements arise, they are documented in quality plans.

6.4 Work Environment and Contamination Control

Facility Controls – 7010036

6.4.1 Work Environment

A work environment suitable for the operation of processes and for achieving product conformance is maintained. This program includes Electro Static Discharge (ESD) controls. Controls include temperature and humidity controlled environment, ESD garments, wrist and heel straps, conductive workstations, carts, chairs and floors. Additional factors include a clean, well-organized and well-lit working environment.

Any additional requirements are determined during quality management system planning and documented in quality plans.

Virtex ensures any personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained employee.

Internal data monitoring and measurement of devices along with customer feedback resulting in failures is evaluated to determine if the work environment is sufficient for achieving product conformance.

6.4.2 Contamination Control

Virtex plans and documents arrangements for the control of contaminated or potentially contaminated product to prevent contamination of the work environment, product and personnel.

7 Product Realization/Operation (8.0)

7.1 Planning of Product Realization

Procedure for Planning of Product Realization- 1010009

Configuration Management – 1010004, Project Management Procedure- 1010011, Risk

Management – 7010071, Configuration Management – 1010004, *Disaster Plan Process – 9010002, Purchasing – 2010004,* Counterfeit Electronic Component Avoidance Procedure- 2010012

Quality planning of product is required prior to release of an order by a new customer, of a new assembly, or of implementation of new processes. Quality planning of product is performed according to the Planning of Product Realization procedure, as appropriate. During this planning, the Account or Program Manager, along with appropriate resources, shall identify and document:

- the quality objectives and requirements for the product, which include product and personal safety, reliability, availability and maintainability, producability and inspectability, suitability of parts and materials used, selection and development of embedded software and recycling or final disposal of the product at the end of its life;
- design for Manufacturability and Testability;
- processes, documentation, records, and resources required to achieve conformity and to meet on-time delivery to the product and service and, including resources to support the use and maintenance of the product;
- verification, validation, monitoring, measurement, inspection and test requirements;
- configuration management appropriate to the product, traceability;
- criteria for product and service acceptance, handling and storage;
- determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;
- engaging representatives of affected organization functions for operational planning and control;
- determining the process and resources to support the use and maintenance of the products and services;
- determining the products and services to be obtained from external providers; and
- establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

The output of quality planning of product includes documented quality plans, processes and procedures and the applicable records.

Virtex Program Managers or Account Managers as appropriate, are responsible for assuring product planning and for managing product realization as appropriate to Virtex, customer requirements, and products and services. Virtex manages this in a structured and controlled manner including scheduled events performed in planned sequence to meet requirements at acceptable risk, within resource and schedule constraints. The output of planning of product includes documented quality plans, processes and procedures as required and appropriate records.

Risk management is performed for products and services and includes managing risk to the achievement of applicable requirements, which includes appropriate to Virtex products and services, assigning responsibilities, definition of risk assessment, identification, assessment and communication of risk, implementation, and management actions to mitigate risks that exceed the defined risk acceptance criteria, and acceptance of risks remaining after implementation of mitigating actions. Risk management includes risks, as applicable, relating to product safety. Records of these activities are maintained.

Configuration management is established, implemented and maintained through processes that includes, appropriate to the product, configuration management planning, identification and traceability, change control including documented information ensuring the process is consistent with the actual attributes of the product and services, configuration status accounting and configuration audits.

Established procedures allow for the planning and control of temporary or permanent transfer of work to an external provider and their sub-tier provider when applicable, and for the verification of conformity of the work to requirements. Processes include work transfer from one supplier to another supplier per established purchasing procedures.

Virtex plans, implements, and controls the process, as appropriate to Virtex and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products delivered to the customer.

7.2 Customer-Related Processes

Customer Related Processes - 1010003

7.2.1 Determination of Requirements Related to the Product and Service

Virtex determines and documents customer requirements, including any special requirements and identifies operational risks before acceptance of the purchase order. Customer requirements include those:

- requested by the customer;
- required for delivery and post-delivery activities;
- not stated by the customer but necessary for specified use or known and intended use;
- statutory and regulatory requirements related to the product;
- any user training needed to ensure specified performance and safe use of the medical device; and
- any additional requirements determined by Virtex

Customer requirements are determined according to the Customer Related Processes procedure.

7.2.2 Review of Requirements Related to the Product and Service

Virtex has a process in place for the review of requirements related to the product which includes applicable functions of Virtex. The review is conducted before the order is accepted. The process ensures that:

- product requirements are defined and documented;
- if upon review Virtex determines that some customer requirements cannot be met or can only be partially met, Virtex negotiates a mutually acceptable requirement with the customer;
- contract or order requirements differing from those previously expressed are resolved;
- Virtex has the ability to meet the defined requirements including applicable regulatory;
- any user training needed to ensure specified performance and safe use of the medical device is available or planned to be available;

- special requirements of the product are determined and risks identified;
- records are maintained showing the results of the review and any actions arising from the review;
- where a customer does not provide a documented statement of requirement, or the requirements are not fully defined, the customer requirements are confirmed before acceptance; and
- when product requirements are changed, Virtex communicates changes to relevant personnel and amends relevant documents.

7.2.3 Communication

Project Management Procedure- 1010011

Customer Complaint Handling Procedure-7010069

Virtex has implemented an effective process for communicating with customers in relation to:

- product and service information - handled through Virtex's Account/Program Manager and communicated to the appropriate individuals throughout the organization;
- inquiries, contracts and order handling, including amendments, communication methods regarding regulatory requirements, Virtex's Account/Program Manager ensures proper communication and follow-up of completion; and
- customer feedback, including customer complaints/returns - communicated to Virtex's Account/Program Manager, who is responsible for documenting the results and forwarding to the Quality Department for action, as appropriate.

7.3 Design and Development

Virtex is not responsible for design or development activities, and therefore claims this section as a permissible exclusion.

Change orders and amendments are processed and reviewed according to the Configuration Management procedure. ECO's are communicated to all functions within the organization that may be affected by the change of customer requirements. A record of the ECO is maintained.

7.4 Purchasing/Control of Externally Provided Processes, Products and Services

Purchasing Procedure - 2010004

7.4.1 Purchasing Process

Supplier Performance and Measurement - 2010011

Documented procedures are followed to ensure that purchased product, services and processes conform to the specified purchase requirements. The procedures outline the extent of control required for external suppliers to assure supplier conformity of all products purchased, including product from sources defined by the customer, services and processes. Suppliers are evaluated and selected based on their ability to supply product, services and processes in accordance with requirements as outlined in the procedure, and are based on the effect of the purchased product of the medical device and are appropriate to the risk associated with the medical device. Virtex defines the

requirements necessary for external providers for controlling documented information created by and/or retained by external providers. Externally provided products, services and processes include the criteria for selection, evaluation, re-evaluation, and determination and management of risk are identified and documented, including where required, use of approved special process sources by Virtex and selected suppliers. This process, responsibilities, and authority for approval status decision, along with changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, are documented. Virtex requires all external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that the requirements are met. A register of approval status is maintained, along with the scope of approval. Periodic review of supplier performance, including product, service, and process conformity, and on-time delivery performance, is used to establish necessary controls to be implemented. Records of the evaluation and any necessary actions taken when requirements are not met, are maintained as quality records.

7.4.2 Purchasing Information/External Control

Purchase Order Creation-2010006
Customer Approved Vendor List – 2010010
Counterfeit Electronic Components Avoidance Procedure -2010012

Purchasing information describes the external provider's products, services, and processes to be purchased including, where appropriate;

- identification of relevant technical data;
- requirements for approval of product, services, processes and equipment, performed according to the risks identified by Virtex;
- requirements for qualification of personnel;
- quality management system requirements;
- prevent the use of counterfeit parts;
- communication to external providers the awareness of their contribution to product, service, or process conformity, product safety and the importance of ethical behavior;
- the results of periodic review of performance;
- design and development control;
- the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data;
- requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics;
- requirements for test specimens for design approval, inspection/verification, investigation or auditing;
- inspections or tests, as appropriate, when there is a high risk of nonconformities including counterfeit parts;
- requirements regarding the need for suppliers to notify Virtex of nonconforming processes, products, or services obtain our approval for nonconforming product

disposition and notify Virtex of product and service process changes, or changes from suppliers in writing prior to implementation for those changes that affect the ability to provide product that meets the PO requirements, changes of manufacturing facility locations and, where required, obtain approval, and flow down to the supply chain the applicable requirements including customer requirements;

- record retention requirements including disposition requirements and;
- Right of access by Virtex, our customer and regulatory authorities to the applicable area of all facilities, at any level of the supply chain involved in the order and to all applicable records.

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier. For traceability purposes, purchase orders are considered quality records.

7.4.3 Verification of Purchased Product

Receiving Procedure – 7010044
Inspection Procedure (Turn-Key) - 7010006

The Receiving Inspection - Turnkey procedure describes the process used to verify that purchased product meets specified purchase requirements, and includes review of required documentation and certain levels of inspection of product upon receipt. When Virtex becomes aware of changes to purchased product it is determined whether the changes affect the product realization process or a medical device. If verification of product prior to its shipment to Virtex is required, the requirements will be documented on our purchase order to the supplier. A register of delegation and all records maintained.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision-General Requirements –

Control of Production Service Provision – 7010037

Virtex plans and carries out production and servicing, when applicable, under controlled conditions. Controlled conditions include, as applicable:

- the availability of information that describes the characteristics of the product and the results to be achieved;
- the availability of documented procedures and work instructions, including workmanship criteria for acceptance and rejection, reference materials and reference measurement procedures as necessary at appropriate stages to verify that criteria for control of processes or outputs and acceptance criteria for products and services have been met;
- the availability and use of suitable monitoring and resources;
- the availability and use of monitoring and measuring devices;
- the implementation of specific monitoring and measurement equipment required and instructions associated with their use;
- the implementation of release, delivery and post-delivery activities;
- accountability for all product during production, including parts quantities, split orders and nonconforming material/product;

- evidence that all product and inspection/verification operations have been completed as planned, or as otherwise documented and authorized including measurement results to be retained;
- provision for the preventive, detection and removal of foreign objects;
- monitoring and control of utilities and supplies to the extent they affect conformity to product requirements;
- the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that product does not meet requirements;
- establishing, control and monitoring, implementing, and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified;
- designing, manufacturing and using tooling to measure variable data;
- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization;
- ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use;
- planning of special processes, including validation and controls, as appropriate;
- the implementation of defined operations for labeling, packaging, and release ;
- the establishment, maintenance and retention of a Device History Records for medical product.

7.5.2 Cleanliness of Product

Facility Control Procedure -7010036

Where processing agents are used during manufacture and subsequent removal is required, departmental procedures address the removal process. Purchasing alerts suppliers that processing agents must be removed from fabricated products prior to delivery unless otherwise indicated. Any products, manufactured or purchased, exhibiting residual processing agents are handled according to the Control of Nonconforming Material/Product Procedure.

When cleanliness beyond that defined in section 6.4 Work Environment is required, customer, product or process specific instructions are documented. Precautions related to potentially contaminated product are documented in the Return Material Authorization Procedure.

7.5.3 Installation Activities

Virtex is not responsible for installation activities, and therefore claims this section as a permissible exclusion.

7.5.4 Servicing Activities

Procedure for Servicing - 1010013

When servicing of product is requested by the customer, Virtex establishes necessary documents, procedures, work instructions, reference materials and reference measurement procedures as needed to perform the servicing activities and verify the results meet the

specified requirements. Records of servicing activities are analyzed to determine if further action, complaint or process improvement, is required. Records are maintained.

7.5.5 Particular Requirements for Sterile Medical Devices

Virtex does not provide sterile medical devices, and therefore claims this section as a permissible exclusion.

7.5.6 Validation of Processes for Production and Service Provision

Configuration Management-1010004

Validation Process - 7010059

For verification of above planned processes, Virtex uses a representative item from the first production run for all product that are new parts and assemblies to verify that the production processes, production documentation and tooling are able to produce parts and assemblies that meet requirements. This documented information identifying results in retained. This process is repeated when changes occur that invalidate the original results. (e.g. engineering changes, manufacturing process changes, tooling/fixture changes).

Personnel authorized to approve changes to production and service provision changes are identified. Changes are controlled and documented that affect processes, production equipment, tools and software programs. Results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product conformity.

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and is maintained by the appropriate department heads.

Storage requirements, including periodic preservation/condition checks are defined and documented for production equipment or tooling in storage.

Virtex's post-delivery support includes complying with statutory and regulatory requirements, customer requirements including customer feedback and product and service support which includes product authorized for return. When a problem is detected after delivery, Virtex takes appropriate action including assisting in investigation and reporting as applicable.

Virtex validates any software or processes, typically referred to as special processes, for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or delivered. Validation demonstrates the ability of these processes to achieve planned results. These processes are often referred to as special processes.

Virtex has documented the process for validation including;

- defined criteria for review and approval of the processes, including changes;
- approval of equipment and qualification of personnel;
- use of specific methods and procedures;
- requirements for records, including the maintenance of such records; and

- revalidation.

7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

Virtex does not provide sterile medical devices, and therefore claims this section as a permissible exclusion.

7.5.8 Identification

Product Identification and Traceability – 7010032
Final Inspection Procedure – 7010004
Test Operating Procedure - 8010005

Virtex identifies all material throughout all production processes according to the Product Identification and Traceability procedure. A sequential record, Job Traveler, of the production of product is maintained and retrievable. Virtex maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the agreed upon required configuration. As required by our customer, Virtex may be required to add a unique device identification to a medical device.

Product is identified regarding status of monitoring and measurement requirements throughout production and storage. Only product which has passed the required inspections and tests is dispatched or used. When acceptance authority media is used, such as stamps, labels, electronic signatures or passwords, controls for the media are established.

All returned product is identified and distinguished from conforming product according to the Return Material Authorization process.

7.5.9 Traceability

Individual Board to Component Lot Traceability Procedure - 7010074

7.5.9.1 General

Virtex serializes product as required by the customer and maintains lot code traceability of all purchased material. Additional controls are maintained as specified by the customer, or if ISO 13485/AS9100 is required, identification is maintained for the life of the product. Appropriate quality records of traceability are maintained, including a sequential record of a products production operations which is retrievable.

Virtex's traceability procedure provides for traceability to the component level, and to the next higher assembly or box build. When manufacturing product, avionics, aerospace, or defense products, any material and environmental conditions that could cause the device to not satisfy the specified requirements are determined and records kept. Records of shipping information are maintained.

7.5.9.2 *Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices.*

Virtex does not provide sterile medical devices, and therefore claims this section as a permissible exclusion.

7.5.10 Customer Property/Property Belonging to Customers or External Providers

Control of Customer Property - 2310009

Virtex exercises care with customer property, including property supplied by external providers as applicable, while it is under the organization's control or use. The Control of Customer Property procedure outlines the identification, verification, protection and safeguarding of customer property, including property supplied by external providers as applicable, provided for use at Virtex. This property includes intellectual property. If customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer and records maintained.

7.5.11 Preservation of Product

Preservation of Material/Product Procedure - 2310008

The Preservation of Material/Product Procedure documents how Virtex preserves the conformity of product during internal processing and delivery to the intended destination, including product with limited shelf-life or that requiring special storage conditions. This preservation includes identification, marking/labeling which includes safety warnings and cautions as applicable, handling including special handling for sensitive products and hazardous materials, cleaning, prevention, detection and removal of foreign objects, packaging and storage, including hazardous materials, including shelf life control and stock rotation and protection. Special handling and storage conditions, including for sensitive products, are controlled and recorded.

7.6 Control of Monitoring and Measuring Equipment/Resources

Control of Monitoring and Measurement Devices - 8010001

Virtex has determined the monitoring and measurements to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure outlines the process used to ensure that monitoring and measurements to be carried out are carried out in a manner that is consistent with the monitoring and measurements requirements, and that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out. A register is maintain for monitoring and measurement equipment and defines the process employed for their recall for calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. Monitoring and measurement equipment includes but is not limited to: test hardware, test software, automated test equipment, and customer supplied equipment used to provide evidence of product conformity.

Where necessary to ensure valid results, measuring equipment is:

- calibrated or verified at specified intervals or prior to use against measurement standards traceable to international or national measurement standards;
- adjusted or re-adjusted as necessary;
- identified to enable the calibration status to be determined;
- safeguarded from adjustments that would invalidate the measurement result; and
- protected from damage and deterioration during handling, maintenance and storage.

In addition, the Quality Department assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Virtex

takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

8 Measurement, Analysis, and Improvement/Performance Evaluation (9)

8.1 General

Quality Management System (QMS) Process Monitoring, Measurement, and Improvement - 7010064
Monitoring and Measurement of Product - 7010065

Virtex has planned and implemented the monitoring, measurement, analysis and improvement processes needed to:

- demonstrate conformity of the product, through the use of first-article, in-process and final inspection procedures. Automated Optical Inspection and X-Ray inspection may also be utilized;
- ensure conformity and continued effectiveness of the quality management system, and continually improve the effectiveness of the quality management system. This is done by individual departments' collection and utilization of measurement and monitoring data, and review of the data at management review meetings;
- Maintain the effectiveness of the quality management system.

This process is identified in documented procedures and includes determination of applicable methods, including statistical techniques, and the extent of their use. Statistical techniques may be used to support design verification, process control including; selection and inspection of key characteristics, process capability measurements, statistical process control, design of experiment, inspection and failure mode, effects and criticality analysis.

8.2 Monitoring and Measurement

8.2.1 Feedback

Customer Satisfaction Procedure - 1010010

As one of the measurements of the performance of the quality management system, Virtex monitors information as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Satisfaction procedure, utilizing the Customer Satisfaction Survey to develop and implement plans for customer satisfaction improvement addressing deficiencies identified by the Customer Satisfaction Surveys and includes verification of the effectiveness of the results. Evaluation of the Customer Satisfaction survey includes, but is not limited to, product/service conformity, on-time delivery performance, customer complaints/returns and corrective action requests. Results of customer satisfaction and/or customer feedback are an integral part of Management Review.

8.2.2 *Complaint Handling*

Customer Complaint Handling-7010069

Virtex's documented procedure for timely complaint handling includes receipt of information, evaluating the information to determine if the feedback constitutes a complaint, including justification if not, investigation, notification to our customer with required information for their reporting to regulatory authorities, handling complaint related product, and the need to initiate corrections or corrective actions, including exchanges of information or required actions from external providers.

8.2.3 Reporting to Regulatory Authorities

Customer Complaint Handling-7010069

Customer complaints that represent an event that must be reported to regulatory authorities are the responsibility of the customer as documented on the quotation to the customer.

8.2.4 Internal Audit

Internal Audits - 7010048

Virtex conducts internal audits at planned intervals to determine whether the quality management system:

- conforms to the planned arrangements (see 7.1), to the requirements of ISO 13485:2016, ISO 9001:2015 and AS9100D standards, to applicable statutory and regulatory standards, to customer contractual requirements, and to the quality management system requirements established by the organization, and
- is effectively implemented and maintained.

An audit program has been designed and implemented according to status and importance of the processes and areas to be audited. The audit program identifies the audit schedule, taking into account the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records are defined and documented in the Internal Audit procedure.

Management of the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results. Internal audit results are reported to management during Management Review.

8.2.5 Monitoring and Measurement of Processes

Quality Management System (QMS) Process Monitoring, Measurement and Improvement-7010064

Virtex applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, preventive and corrective action is taken, as appropriate, to ensure conformity of the process and product. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Quality Management System (QMS) Process for Monitoring, Measurement and Improvement, Corrective and Preventive Action and Management Responsibility procedures. In the event process nonconforming is determined, an Virtex Issue Report is issued to take appropriate action, to correct the nonconforming process to evaluate whether the process nonconformity has resulted in product nonconformity, and if the nonconformity is limited to a specific case or whether it could have affected other processes or products, and identify and control any nonconforming product.

8.2.6 Monitoring and Measurement of Product

Monitoring and Measurement of Product - 7010065

Standard Packing and Shipping Procedure - 2010009

Virtex monitors and measures characteristics of the product to verify that product requirements are met. This is carried out at appropriate stages of the product realization process identified in the Job Traveler. Acceptance criteria are defined and are specified in the job folder. Records of product conformance, and product qualification as required, including the person authorizing acceptance and release of product, are maintained. Measurement requirements for product acceptance are documented and include:

- criteria for acceptance and/or rejection;
- where in the sequence measurement and testing operations are to be performed;
- required records of the measurement results; and at a minimum indicate acceptance or rejection; and
- any specific measurement instruments/test equipment required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified Virtex ensures they are controlled and monitored in accordance with established processes.

Should sample inspection be utilized as a means of product acceptance, the sampling plan used will be determined based on recognized statistical principles and appropriate for use.

Should product qualification be required, Virtex assures all records provide evidence that the product qualification meets defined requirements as required by the customer. This includes, when required to demonstrate product qualification, retained documented information providing evidence that the products and services meet defined requirements.

Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority. Where applicable, by the customer, records of such release are identified and recorded to allow recall and replacement if found not to meet requirements. All applicable documentation required to accompany the products and services during shipment are noted and are verified as present prior to shipment.

Records are kept identifying the personnel performing inspection or test.

8.3 Control of Nonconforming Product/Service/Outputs

Control of Nonconforming Material/Product Procedure – 7010034

8.3.1 General

Virtex ensures that products and services which does not conform to product requirements, (non-conforming outputs" which includes nonconforming products and services generated internally, received from an external provider, or identified by a customer) are identified and controlled to prevent its unintended use or delivery, including containment as necessary on other processes, products or services. The controls and related responsibilities and authorities for dealing with nonconforming product, including

nonconforming product returned by the customer, along with the responsibility and authority for review and disposition, and determination of the need for an investigation and notification to external parties responsible for the nonconformity, are defined in the Control of Nonconforming Product procedure.

8.3.2 Actions in Response to Nonconforming Product/Service Detected Before Delivery

Disposition as use as is or repair for product shall only be used after written approval by the customer. Records of the nature of nonconformities and subsequent actions taken including necessary actions to contain the effect of the nonconformity on other processes or product and includes concessions, are maintained.

8.3.3 Actions in Response to Nonconforming Product/Service Detected After Delivery

When nonconforming product is detected after delivery, Virtex takes corrective actions appropriate to the effects/impacts, or potential effects, of the nonconformity and reports to the appropriate persons in a timely manner. All persons requiring notification of nonconforming product can include suppliers, internal personnel and customers.

8.3.4 Rework

Rework and Repair Procedure - 7010050

Concessions are taken only when authorized by the customer and only if regulatory requirements are met. The identity of the person authorizing the concession shall be documented by the customer. The rework process and determination of potential adverse effects has been documented in the same manner as the original instructions. After correction, nonconforming product is subject to re-verification to the requirements.

Product dispositioned as scrap will be conspicuously and permanently marked and positively controlled until it is physically rendered unusable.

8.4 Analysis of Data/Analysis and Evaluation

Quality Management System (QMS) Process Monitoring, Measurement and Improvement-7010064

Monitoring and Measurement of Product - 7010065

Virtex identifies, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for identifying, collecting and analyzing this data is defined in the Quality Management System (QMS) Monitoring, Measurement, and Improvement Procedure. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information and input relating to:

- customer satisfaction/feedback;
- on-time delivery;
- customer complaints, returns, including corrective action requests;
- conformance to product/service requirements;

- characteristics and trends of processes and products including risks and opportunities for preventive action;
- supplier performance;
- audits; and
- servicing reports of data collected for servicing orders.

Records of the data analysis are maintained.

8.5 Improvement/Improvement (10)

Improvement - 7010062

8.5.1 General/General

Virtex's improvements of the effectiveness of the quality management system, through the use of the quality policy, includes quality objectives, audit results, analysis of data and correction, corrective actions, and opportunities for continual improvements Virtex determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. Determining and selecting opportunities includes:

- improves products and services to meet customer requirements as well as addresses future needs and expectations;
- correcting, preventing, or reducing undesired effects;
- improving the performance and effectiveness of the quality management system;
- The effectiveness of the quality management system is reviewed during management review. Virtex plans the implementation of improvement activities, and evaluates the effectiveness of the results.

Virtex communicates with customers regarding any existing or potential adverse events observed during the product realization process. Communication with regulatory authorities is the responsibility of the customer.

Records of all customer complaint investigations, including those where corrective action is determined unnecessary, are maintained. Where activities outside Virtex contributed to the complaint, relevant information is exchanged with the organizations involved.

8.5.2 Corrective Action/Nonconformity and Corrective Action

Corrective and Preventive Action Procedure - 9010000

Virtex takes action to eliminate the cause of nonconformities in order to prevent recurrence, including any arising from complaints. Corrective actions are appropriate to the effects of the nonconformities encountered and shall be taken without undo delay.

A documented procedure defines requirements for:

- Reacting to the nonconformity and taking action to control and correct it, including dealing with consequences;
- reviewing and analyzing nonconformities (including customer complaints/returns);

- determining the causes of nonconformities, including as applicable those related to human factors;
- determining if similar nonconformities exist, or could potentially occur, taking further action when required;
- evaluating the need for action to ensure that nonconformities do not recur;
- determining and implementing action needed, including updating documentation;
- update risks and opportunities determined during planning, if necessary;
- maintaining records of the results of actions taken;
- verifying corrective action taken does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance;
- reviewing corrective action taken for effectiveness;
- flowing down corrective action requirements to the suppliers when suppliers are responsible for nonconformities;
- specific actions where timely and/or effective corrective actions are not achieved; and
- determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

8.5.3 Preventive Action/Continual Improvement

Improvement - 7010062

Virtex continually improves the suitability, adequacy, and effectiveness of the quality management system. Virtex considers the results of analysis and evaluation, and the outputs from management review, to determine needs or opportunities to be addressed as part of continual improvement. Continual improvement activities can include risk management, SWOT (strengths, weaknesses, opportunities, threats) analysis, failure mode and effect analysis (FMEA) lessons learned, and information on product problems reported by external sources. Preventive action and improvements are reviewed so that actions do not adversely affect the ability to meet applicable regulatory and safety requirements and performance of product. Virtex monitors the improvement activities and evaluates the effectiveness of the results. A documented procedure defines requirements and includes these measures and continual improvement activities.

Virtex's Commitment to Quality

Virtex Inc's. Quality Manual defines our quality management system which assures customer satisfaction for all types of product and services provided by Virtex. Virtex strives to produce and continually improve the electronics and electro-mechanical products for our customers that are reliable, safe and meet or exceed customer and applicable statutory and regulatory requirements.