Avnet Technology Solutions (ATS) Business Quality Manual:

ATS Quality Vision:

The Avnet Technology Solutions’ Quality Assurance Team provides a competitive advantage to our trading partners by applying industry leading quality standards ensuring effective and efficient business processes.

Section 1 – Scope

Section 2 – Normative References

Section 3 – Terms and Definitions

Section 4 – Quality Management system

Section 5 – Management Responsibility

Section 6 – Resource Management

Section 7 – Product Realization

Section 8 – Measurement, Analysis, and Improvement

Section 9 – ISO clauses applicable to each Avnet Technology Solutions’ locations.
Section 1 – Scope

The ISO9001:2000 and ISO 13485:2003 standards have been addressed within the ATS business model for the Sale, customer configuration, integration, distribution and services for OEMs, sub-system level computer components, networking equipment, Value Added Resellers, and end-user markets in the computing technology sector.

Section 2 – Normative References


Section 3 – Terms and Definitions

For terms and definitions relating to quality systems, refer to the ISO 9001:2000 or ISO 13485:2003 quality standard; ATS employees may obtain copies from the Document Control Coordinator using the Outlook mailbox: Document-Requests, ATS.
ATS Business Quality Manual

4.0 Quality Management System

4.1 General

Avnet Technology Solutions (ATS) has selected ISO 9001:2000 as its model for Quality Assurance and ISO 13485:2003 for clients within the medical sector. The organization has planned, established, documented, implemented and maintains the business management system, in accordance with these standards with the focus on continual improvement. The organization is committed to improvement of the Business Management System on an ongoing basis.

To this extent, the organization has:

a) Identified the key business processes of the organization that define the scope of the Business Management System (BMS). These key processes are listed within the ATS Business System Overview, document KP03-0002 and this Business Quality Manual.

b) Ensured that the ATS Business System Overview and Business Quality Manual demonstrate the sequence and interaction of the key business processes with the documented Business System.

c) Established the criteria for acceptable business performance through the Strategic Planning Process, document KP01-0001, and review of effectiveness within staff reports, management review, strategic planning and follow-up activities.

d) Annual resource planning activities ensure the availability of resources and infrastructure necessary to support the operation and monitoring of these processes.

e) Put systems in place to measure the effectiveness of business processes and analyze data to support the objectives of the organization during the BMS review.

f) Established the Continual Improvement Process, document KP14-0001, as a result of the analysis of business performance to plans. These processes define the actions undertaken to achieve the planned results and maintain effectiveness of the system.

Where ATS should outsource a key business process that affects product conformity with stated requirements, the organization defines and assures the control of processes and that a Service Level Agreement is completed.

4.2 Documentation Requirements

4.2.1 a) General

TS America’s Quality Policy:

Avnet Technology Solutions will provide defect-free services and products that meet or exceed our commitments to our internal and external customers. We will achieve this through the process of defining and understanding, as well as agreeing and conforming to our customer and quality system requirements.

TS Global Mission:

To lead our industry in growth, innovation, value and effectiveness in such a way that it ensures we are an indispensable element of our suppliers’ customers’ and employees’ success and future dreams.

TS America’s Objectives:

1. Profitable Growth
   - Sell solutions.
   - Sell more to existing customers.
   - Improve margin and value.
   - Recruit new partners and customers.

2. Operational Excellence
   - Deliver the right solution, at the right time, at the right price.
   - Continuously innovate.
   - Create a strategic advantage by providing a seamless customer experience.

3. People Development
   - Attract talent.
   - Retain talent.
   - Develop talent.

4. Customer Engagement
   - Become a leader in world-class service.
   - Grow customers’ businesses.
   - Take cost out of customers’ businesses.

b) Quality Manual

Avnet Technology Solutions (ATS) has documented this quality manual to describe the Business Management System and practices.
c) Documented procedures required for the adopted standards:

ATS has defined the documented key business processes required by the ISO 9001:2000 and ISO 13485:2003 standards as referenced within this manual.

b) Avnet Technology Solutions’ ISO 13485:2003 Scope of Registration:

Arizona, USA – Phoenix & Tempe and Massachusetts, USA – Peabody

Contract Manufacturing of computer systems used in the medical devices.

4.2.2 Business Quality Manual

Copy right in this Business Quality Manual is vested in Avnet, Inc. and any issue of the same is made on the express understanding that it is treated as confidential and that it may not be copied, used or disclosed to others for any purpose except as authorized by Avnet, Inc.

a) Avnet Technology Solutions’ North American ISO 9001:2000 Corporate Scope of Registration:

Sales, custom configuration, integration, distribution and services for OEM’s, sub-system level computer components, networking equipment, Value Added Resellers and End User markets in the computing technology sector.

b) The Key Business Processes that constitute the ATS Business Management System are recorded within the ATS Business System Overview, document KP03-0002.

c) Sequence of the Key Business Processes is also identified within the ATS Business System Overview, document KP03-0002; interrelationship between these processes and sub-processes is demonstrated within the individual Key Business Process documents.

4.2.3 Control of Documents

Master documents supporting the ATS Business Management System that include updates/changes are controlled through the department’s Document Administrator.

Controlled copies of the Key Business Processes are located on the ATS server with access limited to Quality Assurance and Information Technology resources. Paper and/or electronic copies and approvals are maintained and controlled; records are controlled at the departmental level, by trained records administrators. The Control of Documents procedure, KP06-0001 and Control of Records procedure, KP06-0004 detail the requirements for information control and preservation of records. Records of changes to documented processes include the retention of at least one copy of obsolete controlled documents as specified by the customer, regulatory agency, and ATS, as appropriate.

a) The document control procedure specifies approval for adequacy prior to issue. Records are maintained to demonstrate that this has been effectively implemented.

b) The document control procedure provides for review and update of documents, including approval when changes occur. The review and approval of changes are performed by the original approving function, or an alternate qualifying function which has access to pertinent background information upon which to base the decision for a change.

Document Administrators can approve changes that have no impact on the intent of the procedure including spelling errors, paragraph numbering, indentation, format accuracy and revision changes in reference to document names and numbers.

c) Only the copy posted on the server is considered controlled. Printed copies are not considered controlled.

d) Where reference copies are printed for performing job functions, departmental management shall provide means for assuring only current information has been made available and is being used.
e) Legibility and identification of document status and integrity is maintained electronically. Where hard copies or reference documents are printed, they shall be safeguarded from unauthorized change, as determined by area leadership.

f) Where customer specifications or other documents of external origin are used, area management shall identify those documents to assure appropriate controls are applied for revision control and retention.

g) Controlled documents are posted on the intranet; this prevents inadvertent use of uncontrolled/obsolete documents. Build instructions may be printed from the network at the time of use to assure current revision is being used.

4.2.4 Control of Records

In order to prevent damage, deterioration or loss, ATS has established and maintains documented procedures for the identification, collection, indexing, access, filing, storage, maintenance and disposition of records as specified within the Control of Records procedure, KP06-0004.

Records are maintained to demonstrate conformance to specified requirements and the effective operation of the Business Management System. Applicable records from supplier/subcontractors are also maintained. They are available for review when contractually specified by the customer or their representative.

Records are retained for a period of time at least equivalent to the lifetime of the medical device, as defined by the customer, but not less than two years from the date of product release or as specified by relevant regulatory requirements.

5.0 Management Responsibility

5.1 Management Commitment

Executive Management is responsible for communicating the business quality policy, tracking to objectives, and maintaining a commitment to quality throughout the organization. This is achieved by establishing the Business Management System, deploying it to the Avnet Technology Solutions’ workforce through leadership, and creating information channels to continually improve it. Management:

a) Communicates the importance of meeting customer and statutory/regulatory requirements, including changes to regulatory standards or concerns. This is achieved by establishing documentation that includes the specific build instructions and other controlled documentation.

b) Establishes the quality policy via this Quality Manual and supporting system documentation.

c) Ensures quality objectives are established within the business through the Strategic Planning Process, performance reports, executive management meetings, and business unit reviews.

5.2 Customer Focus

Management is responsible for ensuring customer requirements are determined and met with the goal of enhancing customer satisfaction.

Avnet Customer Loyalty Program, Council, and Concierge feedback is utilized to demonstrate customer satisfaction, dissatisfaction, and improvement opportunities.

5.3 Business Policy

Management assures that the quality policy:

a) Is appropriate to the purpose of the organization.

b) Includes commitment to: i) comply with requirements; ii) maintaining effectiveness, iii) continual improvement of the business management system.

c) Includes framework for communicating and reviewing business quality objectives.

d) Is communicated and understood within the organization.

e) Reviews mission and vision suitability on an annual basis.

5.4 Planning

5.4.1 Quality Objectives

Management has established quality objectives that are identified within the Business Quality Manual and Key Business Processes. Functional performance objectives and measurements may also be visually displayed throughout the facilities or within management reports.

5.4.2 Management has ensured:

a) Business Management System planning is undertaken to achieve the objectives as demonstrated within the Strategic Planning process, document KP01-0001.

b) Business Management System integrity is a critical element of the change management practice.
assures this integrity by management reviews and timely planning.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The organization utilizes job descriptions to define the responsibility and authority for employees throughout the organization. Information contained within the Key Business Processes define the responsibility, authority and the inter-relationship of personnel who manage, perform and verify work affecting quality; particularly those personnel who need the freedom, authority, and independence to:

- Initiate action to prevent occurrence of any nonconformities relating to product, process and the Business Management System.
- Identify and record any problems relating to the product, process and Business Management System.
- Initiate and recommend or provide solutions through designated channels.
- Verify the implementation of solutions.
- Control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

5.5.2 Management Representative

ATS has defined and documented the responsibility, authority and inter-relationship of personnel who manage, perform and verify work-affecting quality as defined by documented procedures. This responsibility is delegated through the organization structure with lines of adequate and continuous control over all activities affecting quality.

Senior Management of ATS has identified and provided the resources required to establish and sustain the Business Management System. Provision of resources includes the assignment of trained personnel for management, performance of work and verification activities including internal quality audits.

Quality management leadership is assigned per business location to serve as the Management Representative.

The Management Representative is responsible for:

a) Ensuring that the Business Management System processes are established, implemented and maintained in accordance with the requirements of ISO 9001:2000 and ISO 13485:2003.

b) Reporting the performance of the Business Management System to executive management,

c) Ensuring the promotion of awareness of customer requirements (including regulatory requirements) throughout the organization. Currently there are no projects requiring special regulatory requirements for medical customers; the Management Representative will solicit feedback from the organization on an ongoing basis, during the Business Management System review process, KP02-0001.

5.5.3 Internal Communication

Management communicates the effectiveness of the Business Management System throughout the organization.

5.6 Management Review

5.6.1 Executive Management reviews the Business Management System periodically to ensure it continues to be suitable and effective in satisfying the requirements of the appropriate ISO standard and the quality policy and objectives.

Management Reviews are conducted by the corporate Management Representative of ATS. Information is gathered from the ATS locations and centralized for review.

Quality Assurance uses this information to monitor effectiveness of the entire system, making recommendations to executive management for Strategic Long Range Planning (SLRP) consideration.

The process detailing the specific requirements for management review is specified in the Business Management System Review process, document KP02-0001. The corporate Management Representative maintains records of the reviews.

5.6.2 Input to management review includes:

a) Audit results (Compliance and Issues recorded).

b) Customer Feedback including Suggestions and Complaints.

c) Process performance and product conformity (RMAs).
d) Status corrective actions/preventive actions (PIR) and Return Material Authorizations (RMAs).

e) Status actions from previous reviews.

f) Business changes that could influence the integrity of the Business Management System (BMS).

g) Recommendations for improvement.

h) New or revised regulatory requirements

5.6.3 Output to management review includes:

Review documentation includes documented evidence of actions and decisions from the management review:

a) Improvements identified to maintain and/or enhance the effectiveness of the Business Management System and processes.

b) Third party improvement requests: Supplier or Customer requested changes that may include product improvements (build instruction changes) business improvements/changes, and feedback from the customer council.

c) Resource needs.

6.0 Resource Management

6.1 Provision of Resources

ATS has a formal program established where the organization determines the resources needed to achieve stated objectives.

a) Resource considerations are made with respect to implementation and maintenance and improvement of its effectiveness.

b) To enhance customer satisfaction and address requirements.

c) To meet regulatory and customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work are selected based on competency, education, training, skills or experience.

6.2.2 Competence, Awareness and Training

Training is designated and controlled per the “Training and Development Process”, Document KP05-0001.

a) ATS has determined the competence of personnel during the employee selection process, as designated within the human resource job descriptions.

b) Annually, during the employee performance review and additionally when appropriate, leadership identifies and documents training or development activities to satisfy training and competence needs.

c) Evaluations of action effectiveness are recorded.

d) Through visual management, quality reporting and inclusion of process owners and constituents in process training, employees are made aware of the importance of their activities and the contribution to achieving the business objectives.

e) Records are retained.

6.3 Infrastructure

ATS plans and provides for the organization infrastructure to achieve desired results including conformity to product requirements.

a) Buildings, workspace and utility are planned by the organization and communicated to management; deliverable is the product of the Corporate Real Estate department and is not a function maintained locally.

b) Process equipment including hardware and software used for product realization are planned and provided, where needs analysis demonstrate purpose for adequate processing of goods or services.

c) Communications and infrastructure support are planned by ATS and communicated to management; deliverable is the product of the work team or Corporate Services, dependant on need and outlined per the associated processes on file with Shared Business Services, and KP01-0002 Business Continuity Plan.

6.4 Work Environment

ATS determines the appropriate work environment necessary that ensures product integrity and conformance to requirements. This is accomplished by providing secure areas for product storage, prevention of product deterioration (including packaging and storage,) as well as environmentally sensitive material considerations. This includes provisions for environmentally sensitive materials per procedure titled ESD Procedure, document # WI02-0025.

The organization does not supply invasive medical devices, therefore
work environment controls applicable to devices of that nature in terms of health, cleanliness, and sterilization (and training and monitoring to those requirements) are not applicable.

7.0 Product Realization

7.1 Planning for Product Realization

ATS plans for product realization as demonstrated within the Business Model.

a) Quality objectives are specified within one or more of the following: build instructions, Design Verification, Design Review, CFR file, ER, Customer Inspection Instruction, or other controlled, suitable means. This build documentation contains the necessary information to integrate and ship an order.

b) Equipment, integration process, build specifications and technical considerations are a critical element of the product realization activities and recorded within the ATS build instructions and other build documentation.

c) Being an integrator, the ATS verification, validation, reporting, inspection and test activities are designated on an individual basis according to agreed requirements with the customer. The design element of the business is the integration method and documentation. Verification and validation of product design including risk management, resides with the customer, as the customer maintains design ownership; the Technical Operations Prototype Process, document KP08-0004 includes the review and acceptance.

d) Documentation to demonstrate evidence of satisfactory results of the product realization process are recorded and include pull packets, engineering records, customer acceptance information and quality checklists that are an element of the build instructions.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

Customer requirements definition is initiated during the Discovery Process and recorded within the Order Entry process. ATS provides for product related considerations within the subsequent Business Management System activities to assure the following:

a) Requirements specified by the customer are communicated by various means, which may include but are not limited to, discovery documents, customer supplied documentation including specifications, contracts, agreements, quote requests, and/or purchase orders. All product requirements, including those given verbally, are documented for subsequent review and approval.

b) Where clarification of requirements is needed or unknown requirements become evident, subject matter experts resolve with the customer.

c) Where customer communicates statutory and or regulatory requirements that are above and beyond those provided by manufacturer, consideration to these requirements are documented.

d) Any additional requirements are determined by ATS.

7.2.2 Review of Requirements Related to the Product

ATS reviews requirements of the customer as communicated within the customer’s request for quote. During this discovery process, clarifications are established and agreed when customer places a purchase order and include:

a) Product requirements (parts list)

b) Changes to parts list are reflected in update to the Sales Order and/or Bill of Materials (BOM) and subsequent Avnet Manufacturing Specification or build document.

c) Ability to meet the requirements.

The record of review is the Sales Control Number (SCN) and/or the build instruction and invoice that concur.

Where the customer does not provide a documented requirement, the verbal instruction shall be recorded by ATS and retained as a record; this may be in the form of an order confirmation, memo (email) of understanding, or other suitable means.

Where product requirements are changed, ATS makes necessary updates to internal documents to assure communication of the change to pertinent parties is achieved. Changes may result in updates to Scans, build instruction, using labels, tags, or other suitable means. Change records are maintained and the process recorded within Product Change Request-ECN process, document KP08-0003.

7.2.3 Customer Communication

Lines of communication have been established with the customer in order
to have effective communication through:

a) Product/technical information specialists.

b) Central point of contact has been established in departmental areas (i.e. sales, engineering, etc) for order handling/status/and change requests and disseminating advisory notices.

c) Feedback mechanisms that include conduit for recording suggestions, changes and complaints.

7.3 Design and Development

Avnet Technology Solutions does not design branded product under the name of Avnet. Hence, stated policies found under Design Control are to be considered for internal use only.

7.3.1 Design and Development Planning

The organization plans for and maintains control for the design and development of integration for product realization that includes:

a) Integration design stages supporting customer requirements are recorded in the ATS build instruction document header and planned for integration activities by status via the Embedded Solutions Order Schedule process, document KP10-0001.

b) The organization has established documented procedures for product development activities; design activities reside with the customer. Documentation of requirements for product realization begins during the discovery phase of the sales process. Documentation serves as input for subsequent review, verification, or validation during defined stages that may include: Integration Business Development-Quote Process, document KP08-0005, Technical Operations Prototype Process, document KP08-0004, and/or the First Article and Validate Process, document KP08-0002.

c) Responsibilities for the prototype verification/validation process tasks are assigned within the Technical Operations Prototype Process, document KP08-0004. Product design verification and validation is the responsibility of the customer.

d) Development plans are updated as the project evolves and may include schedule plans, service level agreements, or other suitable means determined by project managers.

7.3.2 Design and Development Inputs

Inputs to Integration design are collected as the result of customer involvement and enter the ATS business through Technical Marketing, Sales, or Engineering during pre-production processes. Inputs may also be provided throughout Technical Operations Prototype process, document KP08-0004, and the First Article and Validate Process, document KP08-0002.

Design input requirements relating to the product, including when appropriate statutory and regulatory requirements are identified by the customer, are documented and their selection reviewed for adequacy.

Customer inputs to the process include functional, performance, and safety/regulatory requirements for intended use that may be impacted by the integration process; customer retains ownership for product design.

Incomplete, ambiguous or conflicting requirements are resolved with those responsible for imposing these requirements.

Contract Review activities are taken into consideration during design input portion of the sales process.

7.3.3 Design and Development Outputs

The output of design and development activities is an approved ATS build instruction that is posted on the ATS server under revision control until "released" to an acceptable level for build. Subsequent changes to product are controlled per the Product Change Request-ECN, document KP08-0003.

a) Review and approval by the customer demonstrates acceptance of the output meeting the customer requirements, including design inputs.

b) The ATS build instruction includes a list of parts necessary for the build. This information, in addition to a Genesis Bill of Materials and subsequent line items on the SCN serves as the basis for material purchase.

c) Acceptance criteria include checklist for product quality and customer acceptance of the prototype via written confirmation or subsequent placement of a purchase order.

d) Being an integrator, specifications of the characteristics essential for the safe and proper use of product resides with our customer.

Records of development outputs are maintained according the Control of Records procedure, document KP06-0004.
7.3.4 Design and Development Review

Technical reviews are performed by subject matter experts and include representatives of functions concerned with the stage(s) being reviewed. Reviews include quotes to determine technical compatibility of the design concept for the customer. Engineering reviews of technical edits are reflected via presence of a build instruction number assignment.

Engineering files serve as the repository for design reviews and include:

a) Evaluation of the ability of the parts list to meet the intended functionality expected by the customer.

b) Proposal of changes or actions necessary to provide an adequate design solution.

7.3.5 Design and Development Verification

Design (prototype) verification is performed as agreed with planned arrangements or as specified by the customer to assure solution integrity. Prototype records and acceptance reports are retained as records of verification activities.

7.3.6 Design and Development Validation

Serving OEM customers, ATS provides product to customers as the result of the Technical Operations Prototype process and the First Article and Validate Process, documents KP08-0004 and KP08-0002, where solution build instructions are validated. For efficiency purposes, product may be available at the ATS lab where customers may validate product on site. Design validation is performed by the customer, in accordance with planned arrangements. Acceptance records obtained from the customer serve as validation of the product and build configuration for ATS.

7.3.7 Design plans are initiated, executed and recorded within the following documents:

- Requirements Development, document KP08-0001
- Technical Operations Prototype Process, document KP08-0004
- Integration Business Development-Quote Process, document KP08-0005
- First Article and Validate, document KP08-0002
- Product Change Request-ECN, document KP08-0003

7.4 Purchasing

7.4.1 Purchasing Process

ATS has established procedures to control the quality of purchased products from franchised suppliers, non-franchised suppliers and value added subcontractors. ATS has established and maintains documented procedures to ensure that purchased product and/or services conform to specified requirements.

The procedure for purchasing is specified in the Material Procurement process, document KP09-0002, and the Supplier Qualification and Disqualification Process, document KP09-0001.

ATS performs evaluations of suppliers/subcontractors in accordance with the procedure listed on the matrix contained in Supplier Qualification and Disqualification Process, document KP09-0001.

ATS evaluates and selects suppliers/subcontractors based on their ability to meet product and quality requirements including quality system and any specific quality assurance requirements unless directed by the customer.

ATS periodically assesses suppliers/subcontractors and reviews product as a means of controlling suppliers and subcontractors. This control is dependent upon the type of product, the impact of the supplied product/service on the quality of the final product and where applicable on the quality audit reports and/or quality records of the previously demonstrated capability and performance of the suppliers/subcontractors.

ATS has established and maintains quality records of acceptable suppliers and subcontractors that are listed within the organization’s order management system, accordance with the provisions set forth within the corporate procedures.

7.4.2 Purchasing Information

Purchasing documents contain information that clearly describes the product to be ordered. This information includes where applicable:

- Type, class, grade or other precise identification.
- Title or other positive identification and applicable issues of specifications, drawings, process requirements, inspection

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instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel, title, number and issue of the quality system standard to be applied.

Due to the nature of the electronic distribution business, purchase orders for standard off-the-shelf product are frequently transmitted by electronic means and product is immediately dispatched. Therefore, for off-the-shelf product, a review and approval of a purchasing document prior to release is not feasible.

For procurement of product with special customer requirements, a review and approval is performed of the purchasing documents for adequate information prior to release.

7.4.3 Verification of Purchased Product

Upon receipt, materials are processed according to the Inbound/Outbound, WI27-0190, for part identification and packaging conformance. When ATS proposes to verify purchased product/services at the supplier/subcontractor, ATS purchasing documents specify these verification arrangements and the method for release of product.

When specified in a contract, the customer/representative shall be afforded the right to verify at the supplier/subcontractor's facility, such verification shall not be used by ATS as evidence of effective control of quality by the supplier/subcontractor.

Records of verification shall be maintained according to the Control of Records procedure, document KP06-0004.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

ATS plans and employs integration under controlled conditions that may include, but is not limited to:

a) Technical information regarding product characteristics as documented within the ATS build instructions.

b) Instructions where necessary to adequately perform work.

c) Equipment suitable for the needed task and desired results and provisions for equipment integrity as outlined per Equipment Calibration & Maintenance Procedure, document KP04-0001.

d) Monitoring and measuring devices.

e) Measurements for monitoring.

f) Processes for the release, delivery, and post sales support as outlined in the Control of Nonconforming Product process, document KP13-0003.

Clauses 7.5.1.2.1 thru 7.5.1.3 are not applicable to ATS business.

7.5.2 Validation of Processes for Production and Service Provision

a) Integration validation is specified within the ATS build instruction that is created as the quality plan per build/order as specified within the Product Integration & Final process, document KP10-0004. Validation records are recorded using the quality checklist, which is a critical element of the build instruction and include:

b) Defined criteria for review and approval defined in the build instruction.

c) Equipment is designated within the build instruction and controlled per the Equipment Calibration & Maintenance process, document KP04-0001.

d) Integration methods and procedures for material processing are established.

e) The records retention chart specifies product related data to be retained.

f) The implementation of defined operations for the labeling and packaging.

7.5.2.2 Re-validation of processes or equipment (including test software) is specified unless deemed and documented as inappropriate.

7.5.3 Identification and Traceability

7.5.3.1 Identification

Identification of product is maintained from receipt, as identified within the following documented processes: Avnet Logistic Services processes, integration and packaging processes.

Medical product that has been shipped and returned to the
organization are identified and distinguished from conforming product.

7.5.3.2 Traceability

Where and to the extent that traceability is a specified requirement, ATS has established and maintains documented procedures for unique identification and traceability of individual product or batches. This includes traceability of system components to the assembly level, where required.

Identification and traceability is recorded; vehicles for communicating identification and traceability are achieved by various means that may include special handling instructions, or product integration documentation.

7.5.3.3 Status Identification

ATS Integration maintains identification of product status throughout production, storage, installation, and servicing of product. This includes inspection and test status. Product is only released after it has met all inspection & test criteria; where deviation to a process is required, it is documented through issuance of a Quality Bulletin, as described in document WI02-0006. ATS does not manufacture or integrate implantable devices.

7.5.4 Customer Property

ATS establishes and maintains documented procedures for the verification, storage and maintenance of customer supplied product provided for incorporation into the supplies or related activities.

Customer Owned Inventory (COI) is processed in accordance with the Avnet Logistics Services processes.

Any customer-supplied product that is lost, damaged or is otherwise unsuitable for use is recorded and reported to the customer as specified in the procedure. Damaged or unsuitable product is managed via the Control of Nonconforming Product Procedure, document KP13-0003

Verification by ATS of customer-supplied product does not absolve the customer of the responsibility to provide acceptable product.

7.5.5 Preservation of Product

Avnet safeguards product to assure integrity is maintained from receiving to shipping to the customer. Environmental controls prevent inadvertent damage in facility, packaging methods assure shipping integrity and handling methods are in accordance with manufacturer recommendations where designated appropriate.

Avnet has established and maintains documented procedures for handling, storage, packaging, preservation and delivery of product.

Avnet has established methods of handling product to prevent damage and/or deterioration.

Avnet uses designated storage areas and stockrooms to prevent damage or deterioration of product, pending use and delivery. Appropriate methods for authorizing receipt to and dispatch from such areas are as specified in the Inbound/Outbound, WI27-0190.

Avnet controls packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

Avnet facilities apply appropriate methods for preservation and segregation of product.

Avnet arranges for the protection of the quality of product after final inspection and test. When contractually specified by the customer, this protection is extended to include delivery to destination.

7.6 Control of Monitoring and Measuring Devices

Subject matter experts determine the monitoring and measurements activities appropriate to demonstrate conformity of product to predetermined requirements that are documented within the ATS build instruction or subsequent Customer Inspection Instructions.

Equipment used for validation or verification is subject to calibration and maintenance as outlined per Equipment Calibration & Maintenance Procedure, document KP04-0001. The provisions set forth within this process ensure:

a) Calibration frequency is designated and calibration is traceable to recognized measurement standards; where alternate methods are used, methods and acceptability is recorded.

b) Adjustments are performed as necessary.

c) Calibration status.

d) Safeguard equipment from adjustments that could invalidate results.
e) Safeguard equipment from damage. Records of calibration results and adjustments are maintained per procedure and used for determining necessary action for out of tolerance conditions affecting product.

Where equipment is found to not meet requirements, corrective and preventive actions shall be recorded and include provisions for traceability and recall, as appropriate.

8.0 Measurement, Analysis, and Improvement

8.1 General

a) ATS plans and implements monitoring and measurement during the realization of product throughout the: prototype, first article, integration and build processes.

b) Results of Internal Audits are measured in terms of compliance, timeliness, opportunities for improvement and repetitive issues.

c) Internal Audits are conducted with the goal of continually improving business processes.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

ATS continually seeks feedback from customers to determine if their requirements are achieved. This feedback takes place during the prototype process and post build vehicles for product, process and business related feedback.

Customer Advisory Council and Avnet Customer Loyalty Program activities serve to proactively seek feedback from customers on a regular basis.

Corrective and preventive actions are recorded within reports and the Process Improvement Request process.

8.2.2 Internal Audit

ATS utilizes quality planning to establish internal audits on a regular basis. Audit planning activities assure key business processes within the Business Model and Business System are subject to audit annually.

ATS has established and maintains documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system as specified in the procedure listed within the ATS Business System Overview, document KP03-0002.

a) The Internal Business Assessment process, document KP12-0001 assures the assessments include conformance to the ISO 9001:2000 and ISO 13485:2003 Standard, as well as the requirements of the organization that are designated by Process Owners via the established process document.

b) The audit program shall be implemented in accordance with the stated process and effectively implemented. This is demonstrated within audit reports that are a key element of the Business Management System Review process, document KP02-0001.

8.2.3 Monitoring and Measurement of Processes

Results of audits are recorded, monitored and measured in accordance with the procedure Internal Business Assessment, document KP12-0001 and are brought to the attention of the personnel having responsibility for the area audited.

Management personnel responsible for the area audited take timely corrective action on deficiencies found during the audit as outlined within the Corrective & Preventive Action process, document KP14-0002.

Follow-up audit activities to determine implementation and effectiveness of the corrective action taken are verified and recorded per the procedure.

The results of internal quality audits are reported to the corporate management representative for inclusion in the management review as specified in Business Management System Review process, document KP02-0001.

Where planned results are not achieved, correction and corrective action is taken to assure product conformity is achieved.

8.2.4 Measurement and Monitoring of Product

In-process/final product test and inspection is performed in accordance with planned arrangements to verify that product meets specified requirements. Where regulatory and/or agency requirements are specified for product, records of measurement for compliance and subsequent monitoring for continued compliance shall be recorded.
Appropriate records give evidence of conformity with the acceptance criteria and indicate the person(s) authorizing release of product throughout the prototype, first article, and production processes.

Unless otherwise approved by a relevant authority, where applicable by the customer, product is not delivered until the planned arrangements have been satisfactorily completed.

8.2.4.1 – Product will not be dispatched without assuring that all activities relating to measurement of product for compliance have been completed and requirements satisfactorily achieved.

8.2.4.2 – Not applicable to the ATS business as implantable medical devices are not a product offering.

8.3 Control of Non-Conforming Product

ATS has established and maintains documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or delivery. Control is provided for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming product and for notification to the functions concerned within the following process documents:

- **Inbound/Outbound**, document WI27-0190
- **Product Integration & Final**, document KP10-0004
- **Embedded Solutions Order Scheduling**, document KP10-0001
- **Product Change Request- ECN**, document KP08-0003
- **Failure Evaluation**, document KP13-0001

The responsibility for review and authority for the disposition [including acceptance under concession (only if regulatory requirements are met)] of nonconforming product is defined in procedure Control of Nonconforming Product, document KP13-0003 and other key processes, as appropriate.

a) Action is taken to correct nonconformity in accordance with predetermined arrangements. Nonconforming product is reviewed and disposition in accordance with the documented procedure. Nonconforming product may be:

- Reworked to meet the specified requirements.
- Accepted with or without repair by concession.
- Re-graded for alternative applications.
- Rejected or scrapped.

b) Where customer agrees to accept product that differs from established requirements (including product, packaging, documentation and others), the ATS build instruction is updated and submitted to the customer for review and approval prior to dispatch. This does not apply to product not meeting regulatory requirements which can only be released upon designation by the regulatory body.

c) Where required by the contract, the proposed use or repair of product that does not conform to specified requirements is reported for concession to the customer or customer's representative.

Descriptions of nonconformities that have been accepted and of repairs are recorded in accordance with the procedure listed within the Failure Evaluation procedure, document KP13-0001.

Repaired and/or reworked product is re-inspected in accordance with the designated processes, build instructions and/or applicable quality plans, work instructions and workmanship standards. The documentation for rework is subject to the same review and approval as the original build documentation.

8.4 Analysis of Data

The organization analyzes data to determine the effectiveness of the Business Management System. Analysis of data includes process, product, customer satisfaction (feedback), supplier performance, and trends identifying opportunities for improvement within the business as described in the Analysis of Data procedure, KP13-0004, Records of the analysis of data for these results are maintained in accordance with Control of Records procedure, document KP06-0004.

8.5 Improvement

8.5.1 Continual Improvement

ATS uses as the basis for continual improvement of the effectiveness of the Business Management System:

- **Business Quality Manual**
- **Quality Objectives** (strategic plans)
Audit Results (internal and 3rd party assessments)

Analysis of Data (management reports)

Corrective and Preventive Actions (PIRs)

Management Reviews (executive and staff levels)

Customer complaint investigation: If a customer complaint is not followed by a corrective/preventive action, the reason shall be authorized and recorded.

Notification to regulatory authorities any adverse event notifications required by national or regional regulations.

Advisory notices using the Control of Nonconforming Product procedure, document KP13-0003.

8.5.2 Corrective Action

ATS has established and maintains documented procedures for implementing corrective and preventive action. The requirements for corrective and preventive actions are as specified in the Corrective & Preventive Action procedure, document KP14-0002.

Any corrective or preventive action taken to eliminate causes of actual or potential nonconformities, are to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. This may include departmental tracking systems for error handling and problem solving.

ATS implements and records any changes to the documented procedures resulting from corrective and preventive actions taken.

The procedures for corrective action include:

a) Effective handling of customer complaints and reports of product nonconformities.

b) Investigation of the cause of nonconformities relating to product, process and business management system, and recording the results of the investigation.

c) Evaluating the action needed as outlined within the Problem Solving procedure, document KP13-0002 and recording results of the investigation.

d) Determination and implementation of the corrective action needed to eliminate the cause of nonconformities, including application of controls and updating any necessary documentation to ensure that corrective action is institutionalized and that it is effective.

e) Ensuring that relevant information on actions taken and their effectiveness is reviewed by management review in accordance with the Business Management System Review procedure, document KP02-0001.

8.5.3 Preventive Action

The procedures for preventive action include:

a) Use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities, and items submitted to the Avnet Results Program.

b) Determination of the steps needed to deal with any problems requiring preventive action, including the initiation of preventive action and application of controls to ensure that it is effective as outlined within the Problem Solving procedure, document KP13-0002.

c) Records of results of action taken are in accordance with the Corrective & Preventive Action procedure, document KP14-0002.

d) Recording the results of investigations and action taken.

e) Ensuring that relevant information on actions taken is submitted for management review in accordance with the Business Management System Review procedure, document KP02-0001 and reviewing preventive action taken and its effectiveness.
Section 9 – Applicable ISO clauses per location.

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