QUALITY MANUAL

For All Amphenol Alden Products Operations Globally

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QUALITY POLICY

Amphenol Alden's top and enduring priority is Quality. Through continuous improvement, every Amphenol Alden employee will hold a strong commitment to comply with requirements and to maintain and continuously improve the effectiveness of our quality system. Amphenol Alden will deliver quality, innovation, and value to our customers, in the pursuit of exceeding their expectations of our products and services.

Distribution:

- This manual shall be made available on-line (read only) to all Amphenol Alden's employees.
- The General Manager and the Global Director of Quality Assurance must approve the contents of this manual and any changes.
- All other paper copies shall be considered uncontrolled.

CORPORATE RESPONSIBILITY

Amphenol Alden follows the policies of its parent corporation regard corporate responsibility. The following Policies are available on the Amphenol Corporate Website.

- Code of Business Conduct & Ethics Policy
- Diversity, Equity, and Inclusion Policy
- Anti-Human Trafficking & Slavery Policy
- Global Human Rights Policy
- Supplier Code of Conduct
- Supplier Responsible Labor Policy
- Environmental & Sustainability Policies
- Responsible Minerals Policy (Conflict Minerals)
- Health and Safety Policy

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0. Introduction

General

Amphenol Alden Products Company, here after referred to as Amphenol Alden, is an "Interconnect Solutions Provider" offering connectors, cable assemblies, custom interconnect systems, and contact manufacturing.

Amphenol Alden specializes in the design, development and manufacture of interconnect solutions drawing upon its expertise in electrical, mechanical, plastics and manufacturing engineering relative to Original Equipment Manufacturer (OEM) applications. In house capabilities include solid model design, rapid prototyping, product testing, tool design, tool fabrication, manufacturing process development, and high and low volume production.

Once an interconnect design is known and verified and/or validated, Amphenol Alden procures necessary materials, sets up a manufacturing process and commences manufacturing operations to fulfill customer orders. In house capabilities include wire processing, contact manufacturing, molding, assembly, and testing.

Normative Process Approach

Amphenol Alden uses a process approach when developing, implementing, and improving the effectiveness of the quality management system. The objective is to meet customer and regulatory requirements while ensuring customer satisfaction. The process approach emphasizes the importance of 1) understanding and meeting requirements 2) considering processes in terms of added value 3) obtaining results of process performance and effectiveness 4) improving processes based on objective measurement**.** This is achieved through the implementation of a four-tier quality system. The Amphenol Alden Quality Manual is organized by ISO element in accordance with ISO13485:2016 and identifies the system of processes within the organization. Level 2 procedures establish the processes, their interactions, and their management. (See Section 4.2.2)

Overview of Process Interactions and Controls

Referring to the "core and customer-oriented processes" identified in the Amphenol Alden Process Maps in Section 4 of this manual, CRM/CS (Customer Relationship Management/ Customer Service) carries out the processes of sales, order entry, and customer service. Examples of specific metrics applied to ensure these processes are functioning as intended include turnaround times for loading new and modified products into the ERP system and customer satisfaction surveys. (See also, Section 4.2.1 b).

Engineering receives requests for new or modified designs from customers through CRM/CS. Examples of measures used to control these Design and Development activities include product field performance and complaint data.
The purchasing of materials required for manufacturing is initiated based on the combined output from CRM/CS and Engineering. Controls include such metrics as PPV (purchase price variance), inventory turns, on-time delivery, and supplier quality performance.

Manufacturing is extensively measured and controlled. Resulting data is communicated to employees via display on Facility Boards. Such metrics as on-time delivery, scrap, productivity, customer complaints, are used.

The performance of shipping is measured based on on-time delivery and customer complaint data.

Quality is responsible for Incoming, Inprocess, and Final Inspection, has responsibilities together with Purchasing for supplier management, initiates continuous improvement with Engineering and Manufacturing, manages customer complaints, corrective and preventive actions, and calibration.

1. Scope

The Amphenol Alden Quality Management System is certified to ISO13485:2016 and is compliant with 21CFR Part 820. Applicable Certifications and Registration are identified below.

Certification and Registration	Brockton USA	Hermosillo Mexico	Shenzhen China
ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	X	X	X
FDA Registered 21CFR Part 820 – Quality System Regulations – Good Manufacturing Practices for Medical Devices		X	X

Specific requirements of ISO 13485:2016 that are exempt or not applicable are identified below.

Exclusions and non-Applicability	Brockton USA	Hermosillo Mexico	Shenzhen China
Not applicable clause 4.2.3 **Section e and f** Medical Device File	X	X	X
Justification: AAP does not offer installation or servicing			
Not applicable clause 4.2.5 **Paragraph 3** Control of Records	X	X	X
Justification: AAP does not have records pertaining to confidential health information			
Not applicable clause 6.4.2 **Paragraph 2** Contamination control sterilization	X	X	X
Justification: AAP does not offer sterile products			
Not applicable clause 7.3.6 **Paragraph 3** Design and development verification	X	X	X
Justification: AAP does not verify the design outputs against the design inputs of a medical device when connected or interfacing with another device			
Not applicable clause 7.3.7 **Paragraph 4&5** Design and development validation	X	X	X
Justification: AAP does conduct clinical evaluations and does not verify the design outputs against the design inputs of a medical device when connected or interfacing with another device.			
Not applicable clause 7.5.3 Installation	X	X	X
Justification: AAP products do not require installation			
Not applicable clause 7.5.4 Service	X	X	X
Justification: AAP products do not require service			
Not applicable clause 7.5.5 & 7.5.7 Sterilization	X	X	X
Justification: AAP not responsible for sterilization			
Not applicable clauses 7.5.9.2 & 8.2.6 **Paragraph 4** Implants	X	X	X
Justification: AAP products are not implantable			
Not applicable clause 8.2.3 Reporting to regulatory authorities	X	X	X
Justification: AAP does not directly report to regulatory authorities, it is done through our customers			

This manual defines the quality system requirements for Amphenol Alden and describes the authorities and responsibilities of the management personnel responsible for the system. The manual is divided into eight sections. Each section identifies the company policy and commitment to implement the basic principles of the quality system and includes general information as to how the policies are carried out and identifies quality system procedures that include the specific detail for executing the intent of each policy.

2. Normative References

ISO13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
21CFR Part 820 – Quality System Regulations – Good Manufacturing Practices for Medical Devices
ISO14971:2019 Medical Devices – Application of Risk Management to Medical Devices
IPC/WHMA-A-620 Requirements and Acceptance for Cable and Wire Harness Assemblies

3. Terms and Definitions

For the purposes of this manual, the terms and definitions given in ISO9000 and ISO13485 apply.

4. Quality Management System

4.1 General

Amphenol Alden has established, documented, and implemented a quality management system that maintains and measures its effectiveness by monitoring planned results and by ensuring that product conforms to specified requirements. Amphenol Alden's Quality Manual complies with the requirements of the International Standard ISO13485:2016 and 21CFR Part 820.

a) Amphenol Alden establishes, implements, and maintains any requirement, procedure, activity, or arrangement required to be documented.

b) Amphenol Alden has taken the role of the manufacturer with the responsibility for the design and/or manufacture of a medical device**.**

c) Amphenol Alden determines the organizational processes needed for the quality management system as outlined in the Amphenol Alden Process map (Refer to Section 4, Amphenol Alden Products Process Map).

d) Amphenol Alden has applied a risk-based approach to the control of the appropriate processes needed for the quality management system (Refer to section 7.1 & 7.3)

e) The sequence and interaction of these processes are outlined on the Amphenol Alden process map (Refer to Section 4, Amphenol Alden Products Process Map).

f) Amphenol Alden organizational processes have established goals and objectives to ensure that the implementation and control of these processes are effective. For this purpose, Amphenol Alden collects and uses process data to analyze and improve organizational performance. Sources of information that provide data to measure and monitor our organizational processes include but are not limited to: Database reports, Management Review, Audit Results, Plant board with objectives and goals. (Reference: Section 4.2.1 b.).

g) Amphenol Alden ensures the availability of resources and information necessary to support the operation and monitoring of these processes. Reference: Appendix A

h) Amphenol Alden monitors, measures, and analyzes these processes where applicable. See also Introduction section – Overview of Process Interactions and Controls.

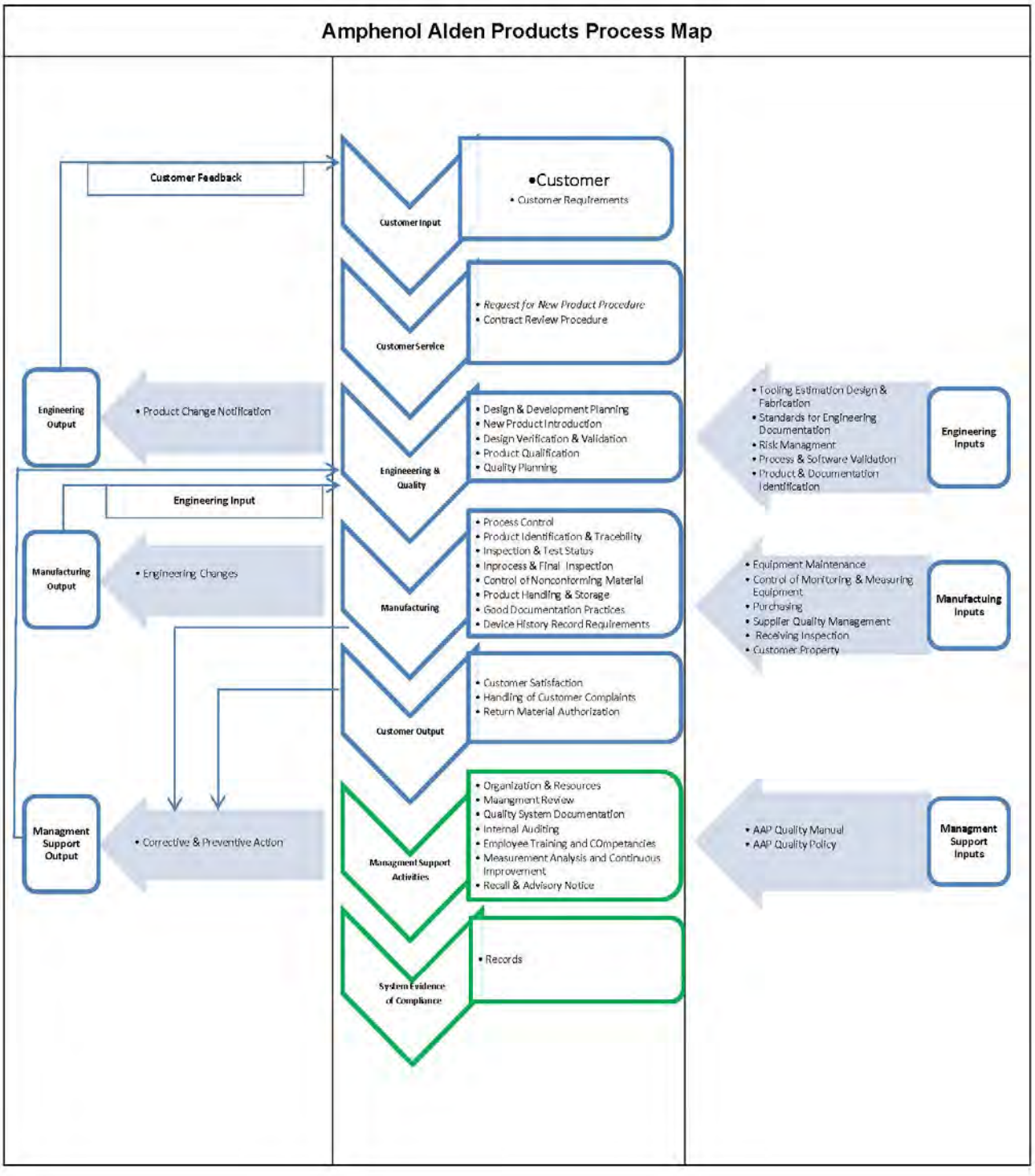
i) Amphenol Alden implements actions necessary to achieve planned results and maintain the effectiveness of these processes. Reference: Appendix A

j) Amphenol Alden ensures that records are established and maintained so that they demonstrate conformance to Amphenol Alden's quality management system and ISO 13485:2016.

k) Amphenol Alden ensures that changes made to the quality management systems processes are evaluated for their impact on the quality management system, evaluated for their impact on the medical devices produced under this quality management system, and are controlled in accordance with the requirements of ISO 13485:2016. Reference Appendix A

l) Amphenol Alden ensures control over outsourced processes that affect product conformity with requirements. The type and extent of control to be applied to these outsourced processes shall be defined within the Quality Management System. See Section 7.4.4 of this manual. Reference Appendix A

m) Amphenol Alden implements validation of the application of computer software used in the quality management system. Reference Appendix A


Amphenol Alden Products Process Map
Customer Feedback
Customer Input
•Customer
• Customer Requirements
Customer Service
• Request for New Product Procedure
• Contract Review Procedure
Engineering Output
• Product Change Notification
Engineeering & Quality
• Design & Development Planning
• New Product Introduction
• Design Verification & Validation
• Product Qualification
• Quality Planning
• Tooling Estimation Design & Fabrication
• Standards for Engineering Documentation
• Risk Managment
• Process & Software Validation
• Product & Documentation Identification
Engineering Inputs
Engineering Input
Manufacturing Output
• Engineering Changes
Manufacturing
• Process Control
• Product Identification & Traceability
• Inspection & Test Status
• Inprocess & Final Inspection
• Control of Nonconforming Material
• Product Handling & Storage
• Good Documentation Practices
• Device History Record Requirements
• Equipment Maintenance
• Control of Monitoring & Measuring Equipment
• Purchasing
• Supplier Quality Management
• Receiving Inspection
• Customer Property
Manufactuing Inputs
Customer Output
• Customer Satisfaction
• Handling of Customer Complaints
• Return Material Authorization
Managment Support Output
• Corrective & Preventive Action
Managment Support Activities
• Organization & Resources
• Maangment Review
• Quality System Documentation
• Internal Auditing
• Employee Training and COmpetancies
• Measurement Analysis and Continuous Improvement
• Recall & Advisory Notice
• AAP Quality Manual
• AAP Quality Policy
Managment Support Inputs
System Evidence of Compliance
• Records

4.2 Documentation Requirements

4.2.1 General

Amphenol Alden has established:

a.) Quality Policy - Top Management is committed to compliance with ISO 13485:2016 and to maintaining the effectiveness of the quality management system.

Amphenol Alden's quality policy was formulated by members of the Management Team and approved by the General Manager. This policy is communicated to employees during orientation training and retraining sessions; communication is reinforced by posted copies in conspicuous locations throughout the company.

b.) Quality Objectives - Amphenol Alden has established quality and business objectives and deployed them throughout the organization. These requirements flow down to the departments and individual level through the use of "target agreements, goals and KPI" which establish objectives in support of the corporate goals.

c.) Documented procedures and records required by ISO13485:2016 and 21CFR Part 820.

d.) Documents including records determined to be necessary to ensure the effective planning, operation, and control of processes.

e.) Documents defining product specifications, quality management system and applicable national or regional regulations requirements such that the complete manufacturing process is defined.

4.2.2 Quality Manual

Amphenol Alden has a documented quality system as described in in this Quality Manual and the overall Quality System. The structure of the documentation consists of a four-tier system with levels structured as follows:

Level 1: Policies – Quality Manual
Level 2: Procedures and appropriate forms
Level 3: Work Instructions and appropriate forms
Level 4: Records

Also included (not limited to):

a.) Drawings
b.) External documents such as customer supplied specifications, industry standards, etc. are identified and their distribution is controlled.
c.) Software applications and related data

Amphenol Alden has prepared documented procedures consistent with the requirements of ISO 13485:2016 and the Company's stated quality policy. The range and detail of these procedures depend on the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity. Documented procedures may refer to work instructions that define how an activity is performed.

4.2.3 Medical Device File

For each type or family of our products Amphenol Alden maintains a Device Master File that contains or references documents which demonstrate the conformity to ISO 13485:2016 and applicable regulatory requirements. This file includes, but is not limited to:

a.) General description of the medical device intended use/purpose, labelling, instructions for use.
b.) Specifications for the product or product family.
c.) Documents defining the product specifications, work instructions defining the complete manufacturing process (routings), Process Control Plan, Checklist for set ups and first piece release checklists.
d.) Documents defining packaging, storage, handling, and distribution.
e.) Procedures for monitoring and measuring.
f.) Reference Appendix A for applicable procedures

4.2.4 Control of Documents

General

Amphenol Alden has established and maintains documented procedures to control all documents and data that relate to the requirements of this quality system. Documents and data can be in the form of any type of media, such as hard copy or electronic media. Amphenol Alden's Quality System documentation is comprised of the following document types (not limited to):

a.) Quality manual
b.) Operational procedures
c.) Work instructions, process procedures, and related forms
d.) Standards and other reference material
e.) Purchasing documents
f.) Product drawings and specifications
g.) Production and quality plans

Documents of External Origin:

To the extent applicable, documents of external origin such as standards and customer drawings, and all other documents determined by Amphenol Alden to be necessary for the planning and operation of the quality management system are identified and is distribution controlled.

a.) **Document Approval and Issue**

Documents are reviewed and approved for adequacy prior to issue either by the original approving function or another designated function which has access to pertinent background information. Such reviews for adequacy are performed by authorized personnel, prior to issue. Documents of external origin are identified as such and the distribution controlled. Documents shall be legible and readily identifiable. The current revision of documents is maintained and made readily available via computer network or controlled access to hard copies when electronic version is not available to preclude the use of invalid and/or obsolete documents. Procedure guidelines ensure that:

- Pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed. Invalid and/or obsolete documents are promptly removed from all points of issue, use, or ensured against unintended use.
- Any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified or dispositioned.
- Reference Appendix A for applicable procedures

b.) **Document Changes**

Document changes are reviewed and approved by the same function that issued the original document, unless specifically designated otherwise. Where possible, the nature of the change is identified in the document. Obsolete documents are removed from use or suitably identified to prevent unintended use if retained for any purpose. Reference Appendix A for applicable procedures

Amphenol Alden retains a copy of the obsolete controlled documents when required. Documents to which products have been manufactured and tested should be available for the lifetime of the product as defined by Amphenol Alden, but not less than the retention period of any resulting record.

4.2.5 Control of Records

Amphenol Alden has established and maintains documented procedures to define the controls needed for identification, collection, indexing, access, storage, security and integrity, retrieval, retention time, maintenance, and disposition of quality records. Quality records are maintained to provide evidence of conformity to specified requirements and effective operation of the quality system. These records may be in the form of any type of media, such as hard copy or electronic media.

Changes to quality records are performed in accordance with good manufacturing practices and maintained as part of applicable records. Amphenol Alden ensures that quality records remain legible, readily identifiable, and readily retrievable.

Quality records are identified, collected, and maintained by the organization responsible for the task, operation, or activity and shall remain legible, readily identifiable, and retrievable.

The Records procedure provides for:

a.) Pertinent supplier records to be included.
b.) All quality records to be legible and stored / retained in such a way that they are readily retrievable, in facilities that provide a suitable environment to prevent damage, deterioration or loss.
c.) Retention period for quality records to be established and recorded.
d.) Where agreed contractually, quality records are made available for customer evaluation, for an agreed period.
e.) Reference Appendix A for applicable procedures

5. Management Responsibility

5.1 Management Team provides evidence of its commitment to the development and implementation of the quality management system and continually improves and maintains its effectiveness by:

a.) Communicating to the organization the importance of meeting customer as well as applicable statutory and regulatory requirements
b.) Establishing the quality policy
c.) Ensuring that quality objectives are established.
d.) Conducting management reviews
e.) Ensuring the availability of resources
f.) Reference Appendix A for applicable procedures

5.2 Customer Focus

5.2.1 Management Team ensures that customer requirements and applicable regulatory requirements are determined and are met (see 7.2.1 and 8.2.1).

Amphenol Alden has dedicated Customer Service Representatives in all facilities. Amphenol Alden maintains a customer focus through continuous and effective communication with customers. Through this continuous communication Amphenol Alden strives to determine, understand, and meet customer requirements for quality, new product development, logistics, delivery, and any other requirements identified by the customer.

Customer Relationship Management (CRM) interfaces with the customer and ensures that all required documents are available for review. CRM, in consultation with Engineering, Quality and manufacturing, ensures that there are no ambiguous or conflicting requirements, and that Amphenol Alden can satisfy all customer requirements.

Customer Satisfaction

Amphenol Alden strives to achieve the highest possible level of customer satisfaction. Measurements relating to customer satisfaction are part of on-going continual improvement efforts. Amphenol Alden proactively conducts surveys to measure customer perception as to whether customer requirements are fully and totally met. Amphenol

Alden's Management Review also has specific metrics that are used to maintain focus on the customer such as defective parts per million and customer complaints. Amphenol Alden conducts an annual Management Review where a broader range of metrics are reviewed that impact customer satisfaction. Effective arrangements are devised and implemented for communicating with customers.

5.3 The Management Team at Amphenol Alden ensures that the quality policy:

a.) is appropriate to the purpose of the organization.
b.) includes a commitment to comply with requirements and to continually improve and to maintain the effectiveness of the quality management system.
c.) provides a framework for establishing and reviewing quality objectives.
d.) is communicated and understood within the organization, and
e.) is reviewed for continuing suitability.
f.) records of these activities are documented.
g.) Reference Appendix A for applicable procedures

5.4 Planning

5.4.1 Quality Objectives

Management Team ensures that quality objectives, including those needed to meet applicable regulatory requirements as well as requirements for product (see Section 7.1), are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy. The status of the quality objectives is reviewed at least annually in Management Review Meetings. These meetings are documented.

5.4.2 Quality Management System Planning

Amphenol Alden's Management Team ensures that:

a.) The planning of the quality management system is carried out in order to meet the requirements given in Section 4.1, as well as the quality objectives, and
b.) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
c.) To ensure efficient and effective planning, Amphenol Alden defines organizational goals and objectives and evaluates performance data from the products and processes employed. Amphenol Alden's management systematically reviews this data to verify effectiveness and efficiency of the various processes.

5.5 Responsibility, authority, and communication

5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined, documented, and communicated within Amphenol Alden. Customer requirements are determined and

are met through management commitment to the development and implementation of the quality management system and the maintenance of its effectiveness. Responsibility for the overall operations of Amphenol Alden is vested in the General Manager and Functional Team Leaders. They have the responsibility and authority for producing products that meet specified requirements, initiating action to prevent shipment of non-conforming product, identifying, and taking action to correct and prevent recurrence of non-conformities, including verification of the success of these actions.

Top management establishes the interrelation of all personnel who manage, perform, and verify work affecting quality, and ensures the independence and authority necessary to perform these tasks.

Interrelation of personnel who manage, perform, and verify work affecting quality is defined by applicable level 2 procedures. The responsibility, authority and interrelation of other personnel that affect quality are defined through job descriptions.

5.5.2 Management Representative

Amphenol Alden's General Manager has appointed the Global Director of Quality Assurance as the Management Representative (MR) for Amphenol Alden.

Irrespective of other responsibilities, the MR has defined authority for:

a.) Ensuring the processes for Amphenol Alden's quality system is established, implemented, and maintained in accordance with ISO 13485:2016. In this role, he/she will have access to all areas of management where activities relating to this standard are performed.
b.) Reporting on the performance of the quality system to the General Manager and members of Top Management for review and any need for improvement
c.) Acting as a liaison between Amphenol Alden and external parties in matters regarding this standard
d.) Providing an official interpretation of Amphenol Alden's quality system
e.) Ensuring the promotion of awareness of applicable regulatory and customer requirements, as well as Amphenol Alden's quality management system requirements throughout the organization
f.) The Global Director of Quality appoints and documents alternate/deputy management representatives at Amphenol Alden facilities.

5.5.3 Internal Communication

Top management ensures that an appropriate communication process is established within the organization and that communication takes place regarding the effectiveness of the quality management system, for this purpose Amphenol Alden holds employee meetings, as needed, for all direct and indirect personnel.

5.6 Management Review

Amphenol Alden reviews the quality management system at least twice annually to ensure its continuing suitability, adequacy, and effectiveness in satisfying the requirements of this quality manual and Amphenol Alden's stated quality policy and objectives. This review includes various inputs assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Outputs to this meeting are developed.

5.6.1 Review Input

The input from Management Review shall include but is not limited to:
a.) Internal and External Feedback
b.) Complaint Handling
c.) Reporting to regulatory authorities
d.) Audits
e.) Monitoring and measurement of processes
f.) Monitoring and measurement of product
g.) Corrective and Preventive Actions
h.) Action Items from previous management reviews
i.) Changes that could affecting the quality management system
j.) Recommendations for improvements
k.) Applicable new or revised regulatory requirements.

5.6.2 Review Output

The output from Management Review shall include but is not limited to:
a.) Improvements related to maintaining the suitability, adequacy, and effectiveness of the quality management system.
b.) Improvements of products and processes related to customer requirements.
c.) Changes needed to respond to applicable new or revised regulatory requirements.
d.) Resources
e.) Records of Management Review are maintained.

6. Resource Management

6.1 Provision of Resources

Amphenol Alden's General Manager and the Functional Team Leaders determine and provide the resources needed to implement the quality management system, to continually improve and maintain the effectiveness and to meet applicable regulatory and customer requirements. This includes necessary tools and training for quality assurance in design, development, production, and verification activities, including internal quality audits. Personnel assignments are based upon training, experience, and demonstrated ability to perform the task required.

6.2 Human Resources

Personnel performing work affecting conformity to product requirements, directly or indirectly, shall be competent on the basis of appropriate education training, skills, and experience.

Training and qualification of the workforce is important to ensure high product quality and customer satisfaction. Documented procedures are established and maintained for establishing competence, identifying training needs and provide for training of all personnel performing activities affecting quality and ensuring awareness of personnel. Personnel performing specific assigned tasks are qualified based on appropriate education, training and/or experience, as required. Appropriate records of training are maintained.

Amphenol Alden's Management Team:

a.) Determines the necessary competence for personnel performing work affecting conformity to product requirements.
b.) Where applicable provides training or takes other actions to achieve or maintain the necessary competence.
c.) Evaluates the effectiveness of the actions taken.
d.) Ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
e.) Maintains appropriate records of education, training, skills, and experience.

6.3 Infrastructure

Amphenol Alden determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements, preventing mix-ups, and ensuring orderly handling of product. Infrastructure includes, as applicable:

a.) buildings, workspace, and associated utilities
b.) process equipment (both hardware and software)
c.) supporting services (such as transport, communication, and information systems)

Documented requirements are established for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. The requirements shall apply to equipment used in production, the control of the work environment and monitoring and measuring as appropriate. Records of such maintenance are maintained. Reference Appendix A for applicable procedures

6.4 Work Environment and contamination control

6.4.1 Work Environment

Amphenol Alden determines and manages the work environment needed to achieve conformity to product requirements. This is achieved through:

a.) documented procedures to monitor and control the work environment,
b.) the monitoring of the health, cleanliness, and clothing of personnel.
c.) When work is performed temporarily in a special environment, conditions are controlled and supervised by a competent individual**.**
d.) documented requirements for health, cleanliness, and clothing of personnel if contact between personnel the product or work environment could affect device safety or performance (Ex, Environmentally Controlled Areas)
e.) Reference Appendix A for applicable procedures

Note: Work Environment relates to those conditions under which work is performed including physical, environmental, and other factors (such as noise, temperature, and humidity, lighting, or weather).

6.4.2 Contamination Control

Amphenol Alden plans and documents the preparation, segregation, and disposition and control of contaminated or potentially contaminated product to prevent contamination of the work environment, personnel, or product.

7. Product Realization

7.1 Planning of Product Realization

Amphenol Alden plans and develops processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system.

Amphenol Alden conducts risk management in several processes of the product realization process. Records of risk management are maintained.

In planning product realization, Amphenol Alden determines the following, as appropriate:

a.) quality objectives and requirements for the product
b.) the need to establish processes and documents, and to provide resources specific to the products including infrastructure and work environment.
c.) required verification, validation, monitoring, measurement inspection, test, handling, storage, distribution, and traceability activities specific to the product together with the criteria for product acceptance.
d.) records needed to provide evidence that the realization process and resulting product meet requirements (see Section 4.2.5)

(Level 2 procedures are cross referenced in Appendix A)

The outputs of this planning are in a form suitable for Amphenol Alden's method of operations including Engineering documentation, QMS procedures, project plans and meeting minutes. Amphenol Alden has established practices for Risk Management throughout product realization.

7.2 Customer Related Processes

Amphenol Alden determines requirements specified by the customer, including requirements for delivery and post-delivery activities if applicable. Customer requirements are typically communicated via the purchase order and special requirements are included on the product routings and visual work instructions to ensure compliance to those requirements.

7.2.1 Determination of requirements related to the product.

Before the build of product for our customer Amphenol Alden determines:

a.) requirements specified by the customer, including the requirements for delivery and post-delivery activities.
b.) requirements not stated by the customer but necessary for specified or intended use, as known.
c.) applicable statutory and regulatory requirements related to the product.
d.) any additional requirements considered necessary by the organization.

7.2.2 Review of requirements related to the product.

Amphenol Alden reviews the requirements related to the product. This review is conducted prior to Amphenol Alden's commitment to supply a product to the customer (e.g., submission of tenders, acceptance of contracts of orders, acceptance of changes to contracts or orders) and ensures that**:**

a.) product requirements are defined and documented.
b.) contract or order requirements differing from those previously expressed are resolved.
c.) applicable regulatory requirements are met.
d.) Amphenol Alden has the ability to meet the defined requirements.

Records of the results of reviews and actions arising from reviews are maintained.

Where customers provide no documented statement of requirement, the customer requirements are confirmed by Amphenol Alden before acceptance.

Where product requirements are changed, Amphenol Alden ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Communication

Amphenol Alden determines and implements effective arrangements for communicating with customers in relation to

a.) product information
b.) enquiries, contracts, or order handling, including amendments.
c.) customer feedback, including customer complaints.
d.) notification after delivery
e.) advisory notices while Amphenol Alden does not communicate directly with regulatory authorities, Amphenol Alden will communicate with its direct customers regarding any applicable recall and or advisory.

Amphenol Alden designates a Customer Service Representative for each one of its customers.

Contract Review

General

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction. Amphenol Alden has established and maintains documented procedures for contract review and for the coordination of these activities.

Review

Before submission of a quote, or the acceptance of a contract or order, the quote, contract, or order is reviewed by Amphenol Alden.

a.) The requirements are adequately defined and documented. Where no written statement of requirement is available for an order received by verbal means, the sales representative will ensure that the order requirements are agreed to before their acceptance and will create a written record of the order receipt.
b.) Any differences between the contract or order requirements and those
c.) in the tender are resolved
d.) Amphenol Alden has the capability to meet the contract or order requirements.
e.) Reference Appendix A for applicable procedures

Amendment to a Contract

Contract amendments are reviewed and coordinated by Amphenol Alden to ensure amendments are made and correctly transferred to the functions concerned within Amphenol Alden.

Records

Records of contract reviews and amendments are maintained. Channels for communication and interfaces with the customer's organization in these contract matters are established where necessary.

7.3 Design and Development

7.3.1 General

Amphenol Alden has established and maintains documented procedures to plan control and verify the design and development of the product in order to ensure that the specified customer requirements are achieved. Outputs from risk management activities defined and initiated by engineering and are deployed throughout the product realization process where appropriate. Specific requirements for design and development are referenced in Appendix A.

7.3.2 Design and Development Planning

Amphenol Alden's Sales / Marketing Group initiate and submits request for designs to the Engineering Department who create plans and controls each design and development activity. These plans determine:

a.) Design and development stages and associated activities to be performed and define responsibility for their implementation.
b.) The reviews needed at each design and development stage.
c.) The verification, validation, and design transfer activities (see note below) that are appropriate at each design and development stage.
d.) Responsibility and authority for design and development activities which are assigned to qualified personnel equipped with adequate resources.
e.) The methods to ensure traceability of the design and development outputs to the design and development inputs.
f.) Resources needed, including necessary competence of personnel.
g.) Plans are updated as the designs evolves.

Organizational and Technical Interfaces

Amphenol Alden defines the organizational and technical interfaces between different groups, which provide input to the design and development of respective design projects. The necessary information is documented, transmitted, and regularly reviewed.

Planning output is documented, and updated as appropriate, as the design and development progresses.

Note: Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.

7.3.3 Design and Development Inputs

Design input requirements relating to the product, including functional, performance and safety requirements, according to the intended use, and applicable statutory and regulatory requirements, are identified, documented and their selection reviewed for adequacy by Amphenol Alden and approved. Amphenol Alden ensures that all incomplete, ambiguous, conflicting, or unverifiable or unvalidatable requirements are resolved with the customer. Consideration is given to the results of contract review activities.

Where applicable, information derived from previous similar designs is included along with any other requirements essential for design and development including applicable outputs from risk management.

7.3.4 Design and Development Outputs

Design output is documented and maintained in a “Design History File” which includes a checklist of output requirements. Design output is expressed in terms that can be verified and validated against design input requirements. Design output will:

a.) meet design and development input requirements.
b.) provide appropriate information for purchasing and production.
c.) contain or refer to product acceptance criteria.
d.) identify those characteristics of the design that are crucial to the safety and proper functioning of the product (e.g., operating, storage, handling, maintenance, and disposal requirements)

Design output documents are reviewed by Engineering before release. Records of the design and development outputs are maintained.

7.3.5 Design and Development Review

At appropriate stages of design, Engineering will plan and process the projects through configured design phase gates to:

a.) evaluate the ability of the results of design and development to meet requirements.
b.) identify any problems and propose necessary actions.

Participants in the reviews include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel.

Records of the results of the reviews and necessary actions are maintained and include the identification of the design under review, participants involved in the review and the date of the review.

7.3.6 Design and Development Verification

At appropriate stages of design, design verifications are performed in accordance with planned arrangements to ensure that the design and development output meets the

design and development input requirements. Verification plans are documented and include methods, acceptance criteria, and as appropriate, statistical techniques with rationale for sample size. Design verification may include activities such as the following:

a.) Design and process failure modes and effects analysis (FMEA)
b.) Modeling and simulation
c.) Computer aided analysis.
d.) Performing alternative calculations
e.) Comparing the new design with a similar proven design, if available
f.) Undertaking tests and demonstrations
g.) Reviewing the design stage documents before release.
h.) Product Qualification activities are undertaken.

Records, results, and conclusion for design and development verification are maintained, as well as necessary actions.

7.3.7 Design and Development Validation

Design validation is performed in accordance with planned and documented arrangements to ensure that the resulting product conforms to defined design input requirements. Wherever required, design validation follows successful design verification. Verification plans are documented and include methods, acceptance criteria, and as appropriate, statistical techniques with rationale for sample size. Validations are performed on representative product, and rationale for the choice of product used for validation is recorded.

Amphenol Alden does not warrant fitness for use in customer's application; however, multiple validations can be performed if required by the customer. Validations are completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

7.3.8 Design and development transfer

Amphenol Alden documents the process for the transfer of design and development outputs to manufacturing. This process ensures that the design and development outputs are verified as suitable for manufacturing before becoming final product specifications and the production capability can meet product specification. Records and conclusion of this transfer is recorded.

7.3.9 Control of Design and Development Changes

Amphenol Alden has procedures and processes to control design and development changes. Amphenol Alden determines the significance of the change regarding function, performance, usability, safety and applicable regulatory requirements for the product and its intended use.

Design and development changes are identified, and records maintained.
The changes are reviewed, verified, and validated, as appropriate, and approved before

implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered, as well as the inputs or outputs of the risk management and product realization process.

All Engineering changes and other certain changes that occur after a final design is released are reviewed and approved by authorized personnel before their implementation. Records of their changes, review and any necessary actions are records and maintained.

7.3.10 Design and development files

For each type or family of our products Amphenol Alden maintains a Device Master File that contains or references documents which demonstrate the conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 Purchasing Process

Amphenol Alden has established and maintains documented procedures to ensure that purchased product (hardware, raw material, service, or a combination thereof) and outsourced processes (plating, color compounding, and PCB assembly), conform to specified purchase requirements. Reference Appendix A for applicable procedures

Evaluation and selection of suppliers

Amphenol Alden has established criteria for the evaluation, re-evaluation and selection of suppliers which are based on:

a.) The supplier's ability to provide product that meets Amphenol Alden's requirements.
b.) The performance of the supplier
c.) The effect of the purchased product on the quality of Amphenol Alden's product
d.) The proportionate risk associated with Amphenol Alden's product.
e.) Supplier evaluation and monitoring is the joint responsibility of Purchasing and Quality Assurance.

Amphenol Alden monitors and re-evaluates suppliers. Monitoring includes supplier performance in meeting the requirements for the purchased product, and the result of this monitoring provides input into the supplier re-evaluation process.

Amphenol Alden ensures that non-fulfillment of purchasing requirements are addressed with the supplier proportionate to the risk associated with the purchased product and in compliance with applicable regulatory requirements.
Records of supplier evaluation, selection, and performance monitoring and re-evaluation of supplier capability or performance and necessary actions arising from these activities are maintained and recorded.

7.4.2 Purchasing Information

Amphenol Alden purchasing documents contain data clearly describing or referencing the product or service ordered, including where applicable:

a.) The part number, revision, description, type, class, grade, or other precise identification
b.) Applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel
c.) The title numbers and issue of the quality system standard to be applied
d.) Applicable special instructions and requirements

Amphenol Alden has purchasing information that includes, as applicable, a written agreement that the supplier notify Amphenol Alden of changes to the purchased product. Prior to the implementation of any changes that affects the ability of the purchased product to meet specified purchasing requirements.

Amphenol Alden reviews and approves purchasing documents for adequacy of the specified requirements prior to release.

To the extent required for traceability, Amphenol Alden maintains relevant purchasing information (i.e., documents and records).

7.4.3 Verification of Purchased Product

Amphenol Alden establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Verification activities are done in accordance with risk management activities and are proportionate to the risks associated with the purchased product.

When Amphenol Alden becomes aware of changes to the purchased product, we determine whether the changes affect the product realization process or the medical device.

a.) Verification at Subcontractor's Premises (Source Inspection)
When source inspection is required, arrangements for verification and method of product release are included in the purchasing documentation.

b.) Customer Verification of Subcontracted Product
When specified in the contract, Amphenol Alden's customer may verify product conformance at Amphenol Alden and/or Amphenol Alden's suppliers. Such verification will not be used by Amphenol Alden as evidence of effective control of quality by its suppliers nor absolve Amphenol Alden's responsibility to provide acceptable product or preclude subsequent rejection by the customer.

c.) Records of verification are maintained.

7.4.4 Control over Outsourced Processes

Amphenol Alden exercises control over outsourced processes, all products received at Amphenol Alden from an outsourced process is subject to Inspection; all requirements must be met in order to release the product to the next stage of the product realization process,
Objective evidence to assure that all requirements are fulfilled is required to assure that all characteristics of the product comply with the applicable specifications (Certificates, Physical Samples, Product related data, etc.). Reference Appendix A for applicable procedures.

7.5 Production and Service Provision

Process Control

Amphenol Alden identifies and plans the production processes, which directly affect quality, and ensures that these processes are carried out under controlled conditions. Reference Appendix A for applicable procedure
Production controls include the following:

a.) Procedures defining the manner of production are specified in the shop order / instruction sheets and assembly drawings prepared by the engineering department.
b.) Availability and use of suitable production equipment and suitable work environment is carried out in accordance with engineering planned requirements as shown in the shop order.
c.) The availability and use of monitoring and measuring devices.
d.) Compliance with product specifications, reference standards / codes, quality plans and/or documented procedures are verified via first piece inspection, process control plans, and final inspection plans.
e.) Product characteristics are monitored, measured, and controlled, wherever deemed necessary, through the use of process control charts.
f.) Setup, monitoring, measuring and control of suitable process parameters accomplished through tools such as the Injection Molding Data Sheets (IMDS) and automated feedback process controls.
g.) Criteria for workmanship are stipulated in a clear and practical manner, through the use of Industry recognized standards such as IPC/WHMA-A620 Requirements and Acceptance for Cable and Wire Harness Assemblies
h.) Suitable maintenance of equipment to ensure continuing process capability is carried out in accordance with procedure OP 2.09.01, Equipment Maintenance
i.) The implementation of release and delivery activities
j.) The implementation of defined operations for labeling and packaging
k.) Appropriate qualification of infrastructure

Records are maintained for qualified processes, equipment, and personnel, as appropriate.

7.5.1 Control of Production and Service Provision

Quality Planning (Product Related)

Amphenol Alden's management team ensures that the planning for product realization is carried out in order to meet all customer requirements and achieve established quality objectives.

Amphenol Alden has defined and documented how the requirements for quality are met. Quality planning is accomplished through a series of activities such as, drawing reviews, product qualification analysis, design phase reviews, inspection, and production planning. The output from these activities results in quality plans that include accepted product drawings, process control plans, and inspection plans.
This procedure provides for consideration to be given to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

a.) The preparation of quality plans
b.) The identification and acquisition of any controls, processes, measuring equipment (including inspection and test equipment), fixtures, resources, and skills that maybe needed to achieve the required quality.
c.) Ensuring the compatibility of the design, the production process, inspection and test procedures and the applicable documentation
d.) The updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation.
e.) The identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed.
f.) The identification of suitable verification at appropriate stages in the realization of product
g.) The clarification of standards of acceptability for all features and requirements, including those which contain a subjective element.
h.) The identification and preparation of quality records
i.) Implementation of product release, delivery, and post-delivery activities (as applicable)

Quality plans may be in the form of a reference to the appropriate documented procedures that form an integral part of this quality system.

7.5.2 Cleanliness of Product

Amphenol Alden ensures and documents the requirements for cleanliness and contamination control of product as required by customer requirements.

7.5.3 Installation Activities (Exclusion)

7.5.4 Servicing Activities (Exclusion)

7.5.5 Particular Requirements for Sterile Medical Devices (Exclusion)

7.5.6 Validation of Processes for Production and Service Provision

Amphenol Alden validates any processes and software for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and consequently, deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Amphenol Alden establishes arrangements for these processes including, as applicable:

a.) defined criteria for review and approval of the processes.
b.) approval of equipment and qualification of personnel
c.) use of specific methods and procedures and acceptance criteria
d.) statistical techniques with rationale for sample size as appropriate
a.) requirements for records
b.) revalidation, including criteria for revalidation.
c.) approval of changes to the processes

Approval of processes and equipment, when appropriate, are carried out through process and/or equipment validation**.**

Amphenol Alden takes a risk-based approach to validation and revalidation. The activities associated with such activities are proportionate to the risks associated with the software and product, as well as the ability of the product to conform to specifications.

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

7.5.8 Identification

Amphenol Alden has established and maintains documented procedures that provide information for product identification throughout product realization processes.

Purchased and in-house manufactured materials and parts are identified with Amphenol Alden and/or customer's part number as assigned by the engineering department. The part number provides for correlation between product specifications and manufacturing/quality records. Reference Appendix A for applicable procedures

Environmental requirements such as REACH and RoHS are identified for material and product when necessary. If required by customer or applicable regulatory requirements a documented system to assign unique device identification (UDI) to the medical device.

Status Identification

Product is identified throughout product realization and subsequent storage to ensure that only product that has passed the required inspections and testing is dispatched. Amphenol Alden uses identification tags such as accepted tags, rejected tags, rework tags, travelers, and quality stamps to identify product status.

7.5.9 Traceability

7.5.9.1 General

Traceability is maintained to shop orders throughout the manufacturing process. For any additional requirements specified by customers, Amphenol Alden has established and maintains procedures that provide for unique identification of individual product or batches.
Instructions for product traceability, including records to be maintained, are set forth in procedure QP 2.08.01 Product Identification and Traceability.

7.5.9.2 Particular Requirements for Implantable Medical Devices General (Exclusion)

7.5.10 Customer Property

Amphenol Alden has established and maintains documented procedures for the control, handling, verification, marking storage disposition and maintenance of customer supplied product including property provided for incorporation into product or for related activities. Product/property that is lost, damaged or otherwise unsuitable for use is recorded and reported to the customer.

When specified in the contract, special handling instructions from customers will take precedent over the company's standard procedures.

7.5.11 Preservation of Product

Amphenol Alden has established and maintains documented procedures as applicable for handling, storage, packaging, preservation, and delivery, to preserve the product during internal processing and delivery to the intended destination to maintain conformity to the requirements. Reference Appendix A for applicable procedures

Amphenol Alden protects product from alteration, contamination and damaged when exposed to expected conditions and hazards during processing, storage, and handling. Methods include, but are not limited to, designing, and constructing suitable packaging and shipping containers, and documenting requirements for special conditions if packaging alone cannot provide preservation. Products are evaluated on a case-by-case basis throughout the product realization process to ensure that preservation is maintained. Special conditions, if necessary, are controlled and recorded.

Handling

Methods for proper handling of product that prevent damage and deterioration including shelf-life practices are documented.

Storage

The stock room and point of use storage areas are used to store product in a manner that prevents damage or deterioration of product pending use or delivery. Storage areas, and appropriate methods for authorizing receipt to and dispatch from such areas, are documented. The condition of the product is assessed at appropriate intervals in order to detect deterioration.

Packaging

Packaging and marking processes, including materials used, are controlled to the extent necessary to ensure conformance to specified requirements.

Preservation

Appropriate methods for preservation and segregation of product are applied as necessary are documented.

Delivery

Amphenol Alden uses high quality packaging materials and well-established packaging methods to ensure the protection of the quality of product after final inspection and test. Where contractually specified, this protection is extended to include delivery to destination.

Amphenol Alden controls product with a limited shelf-life. Any shelf-life requirements for materials and / or products are identified on the controlling specifications.

Reference Appendix A for applicable procedures

7.6 Control of Monitoring and Measuring Equipment

General

Amphenol Alden has established and maintains documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used to demonstrate the conformance of product to the specified requirements. Calibration methods will be traceable to NIST (US), or international equivalent (Mexico & China), in the absence of which, the basis for calibration will be documented. Inspection, measuring, and test equipment is used in a manner that ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Amphenol Alden ensures that measuring equipment is:

a.) Calibrated or verified, or both, at specified intervals or prior to use traceable to NIST (US), or international equivalent (Mexico & China).
b.) Adjusted or re-adjusted as necessary. Adjustments or re-adjustments are recorded.
c.) Identified with its calibration status.

d.) Safeguarded from adjustments that would invalidate the measurement results.
e.) Protected against damage and deterioration during handling, maintenance, and storage.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they are checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, and will be rechecked at prescribed intervals. The extent and frequency of such checks are established, and records are maintained.

In the event that equipment is found not to conform to requirements, Amphenol Alden performs an assessment and records the validity of previous measurements.

Where the availability of technical data pertaining to the inspection, measuring and test equipment is a specified requirement, such data is made available, when required by the customer or customer's representative, for verification that the inspection, measuring and test equipment or device is functionally adequate.

Amphenol Alden may use computer software to aid in the monitoring and measuring of requirements. In the event that computer software is used, Amphenol Alden will validate such software prior to use. Amphenol Alden takes a risk-based approach to validation and revalidation. The activities associated with such activities are proportionate to the risks associated with the software and product, as well as the ability of the product to conform to specifications.

Details of the calibration process and associated records are established. Reference Appendix A for applicable procedures

8. Measurement, Analysis, and Improvement

8.1 General

Amphenol Alden employs suitable methods for monitoring and measurement of the QMS processes, in order to demonstrate the ability of the process to achieve planned results. These monitoring and measurement techniques are required to:

a.) demonstrate conformity to product requirements.
b.) ensure conformity and maintain effectiveness to the QMS as required by ISO 13485:2016 and 21CFR Part 820
c.) ensure a high degree of customer satisfaction.
d.) Reference Appendix A for applicable procedures.

8.2 Monitoring and Measurement

8.2.1 Feedback

As one of the measurements of the performance of the quality management system, Amphenol Alden monitors information relating to customer perception, from production to post-production activities, as to whether the organization has met customer requirements and obtains customer satisfaction feedback to insure, they are satisfied with the service and products supplied by Amphenol Alden.

The methods and feedback system for obtaining and using this information are established to provide early warning of quality problems and for input into risk management for monitoring and measuring product requirements, corrective and preventive actions processes, the product realization process and improvement processes. Reference Appendix A for applicable procedures

8.2.2 Complaint Handling

Amphenol Alden has procedures for timely complaint handling which include requirements and responsibilities for:

a.) Receiving and recording information
b.) Evaluating information to determine if the feedback constitutes a complaint.
c.) Investigating complaints
d.) Determining the need to report the information to the appropriate customers.
e.) Handling of complaint related product
f.) Determining the need to initiate corrections or corrective actions

Amphenol Alden reviews all complaints and performs an investigation is needed. Amphenol Alden will justify if a complaint is not documented and will document any corrective or preventive action.

Any complaints that are determined to be caused from activities outside the organization, relevant information will be shared with the external party involved.
Reference Appendix A for applicable procedures

8.2.3 Reporting to Regulatory Authorities

Amphenol Alden has established and maintains the documented procedures to define requirements for reporting to regulatory authorities about the adverse events or the issuance of an advisory notice. Records of these activities are maintained.

8.2.4 Internal Quality Audits

Amphenol Alden applies suitable methods for monitoring and measuring QMS processes. Internal quality audits are conducted at planned intervals and in accordance with the annual audit schedule to determine the effectiveness of Amphenol Alden's quality system and verify compliance to established quality plans. Detailed information defining

responsibilities and requirements for planning and conducting internal audits, establishing records, and reporting results are documented.
Internal quality audits are scheduled on the basis of the status and importance of the activity to be audited as well as the results of previous audits. The audit criteria, scope, frequency, and methods shall be defined and is carried out by personnel independent of those having direct responsibility for the activity being audited.
The results of the audit are recorded and brought to the attention of the personnel having responsibility for the area being audited. The management personnel responsible for the audited area will ensure that any necessary correction and corrective actions are taken without delay to eliminate detected non-conformities and their causes.

Follow-up audit activities will verify and record the implementation and effectiveness of the corrective action taken.

The results of internal quality audits form an integral part of the input to management review activities.

8.2.5 Monitoring and Measurement of Processes

Amphenol Alden applies suitable methods for monitoring and measurement of its QMS processes to verify that the processes have achieved the planned results or to identify the need for corrective actions as appropriate. Objectives being monitored and measured include:

a.) External PPM
b.) Scrap
c.) Sales
d.) On time delivery
e.) Continuous Improvement

These objectives and goals serve as the link to the core processes of our company and the performance is monitored by the organization.

8.2.6 Monitoring and Measurement of Product

Amphenol Alden has established and maintains documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspection and testing, and the records to be established, are documented in the quality plan or documented procedures. Reference Appendix A for applicable procedures

Inspection and Test Status
Amphenol Alden has documented procedures that ensure inspection and test status of product is identified by suitable means that indicate the conformance or non-conformance of product with regard to inspection and tests performed. The identification of inspection and test status is maintained as defined in the quality plan, and/or documented procedures throughout production to ensure that only product that has passed the

required inspection and test [or released under an authorized concession] is dispatched or used.

Receiving Inspection and Testing

a.) Amphenol Alden ensures that incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements. Inspection plans are created for all part numbers. Verification of conformance is performed in accordance with inspection plan requirements and documented procedures, and test equipment used to perform measurement activities is identified. Non-conforming product is segregated, properly identified, and prevented from use in production.

b.) Amphenol Alden determines the amount and nature of receiving inspection by considering the amount of control exercised at the supplier's premises and recorded evidence of conformance provided. Considering that quality cannot be inspected into the product, Amphenol Alden's strategy is to increase the level of process control at the supplier, thus minimizing the level of inspection required in house.

In-process Inspection and Testing

c.) In-process inspection and test of product is performed as required by the quality plan. Documented procedures provide guidelines for both first piece and in-process inspection. Test equipment used to perform measurement activities is identified.

d.) In-process inspection procedure provides guidelines for holding product until the required tests have been completed.

Final Inspection and Testing

e.) Final inspection and test are carried out in accordance with the documented procedures and applicable inspection plan to complete the evidence of conformance of the finished product to the specified requirements.

f.) Both the inspection plan and the final inspection procedure require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements. Test equipment used to perform measurement activities is identified.

g.) No product is dispatched until all the activities specified in the inspection plan and/or the documented procedures have been satisfactorily completed and the associated documentation is available and authorized. A signed or stamped "Inspected" or "passed" tags by the Final Inspector is placed in each accepted lot and along with other inspection logs, serve as evidence that all inspection plan and procedure requirements have been satisfied.

Inspection and Test Records

Amphenol Alden has established and maintains records, which provide evidence that the product has been inspected and/or tested, these records show clearly whether the product has passed or failed, the inspections and/or tests according to defined acceptance criteria and identify the inspection authority responsible for the release of product and test equipment used to perform measurement activities is identified.
Records for product that fails to pass any inspection and or test is documented.

8.3 Control of Non-Conforming Product

8.3.1 General

Amphenol Alden has established and maintains documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use. This control provides for identification, documentation, evaluation, segregation (when practical), disposition of non-conforming product, and for notification to the functions concerned. When evaluating the non-conformity, an evaluation shall be made in regard to the need for an investigation and notification of any external party responsible for the non-conformity. Notification of external parties shall be documented.

Records regarding the nature of the nonconformities both detected before and after delivery and any subsequent action taken, including the evaluation, any investigation and rationale for decisions shall be maintained.

8.3.2 Actions in response to non-conforming product detected before delivery.

Review and Disposition of Non-Conforming Product

The responsibility and authority for review and disposition of non-conforming product is documented. Non-conforming product is reviewed in accordance with this procedure and may be dispositioned as follows:

a.) Accept as is.
b.) Rework (or repair)
c.) Scrap (precluding its intended use or application)
d.) Return to supplier.

If product is accepted as is, Amphenol Alden provides justification of such concession including the person or personnel authorizing the concession.

Finished product not conforming to customer requirements that is deemed acceptable and compliant to any applicable regulatory requirements is reported for concession to the customer.

8.3.3 Actions in response to non-conforming product detected after delivery.

When nonconforming product is detected or suspected after delivery or use by the customer has begun, Amphenol Alden shall take appropriate actions to the effects, or potential effects, of the nonconformity.

8.3.4 Rework

Rework processes are documented and approved using the same authorization and approval procedure as the original work instruction or as per customer agreements. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product is made and documented. Where contractually required, the proposed use or repair of product which does not conform to specified requirements is reported for concession to the customer. The description of the non-conformity that has been accepted, and of repairs, is recorded to denote the actual condition. Repaired or reworked product is re-inspected in accordance with the quality plan and applicable inspection procedure.

8.4 Analysis of Data

Amphenol Alden collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where/if continual improvement of the effectiveness of the QMS can be made. Information from all parts or the organization is integrated and analyzed.

The results of this analysis are used by Amphenol Alden to determine:

a.) Trends
b.) Customer Satisfaction/Feedback
c.) Conformity to product requirements
d.) Effectiveness and efficiency of the processes
e.) Supplier Quality
f.) Audits
g.) Overall Facility Performance
h.) Conformity and effectiveness of the QMS
i.) Opportunities for preventive actions

Information is presented and analyzed in Management Review meetings. If the analysis of data shows that the QMS is not suitable, adequate, or effective, this shall be an input to improvement activities. Reference Appendix A for applicable procedures

Records of the results of the analysis of data are maintained.

8.5 Improvement

8.5.1 General

Amphenol Alden Management is committed to maintain and continually improve the effectiveness of the QMS. This will be achieved through the implementation and use of the quality policy, quality objectives, audit results, post market surveillance (feedback), analysis of data, corrective and preventive actions and management review.

Amphenol Alden identifies and implements any changes necessary to ensure and maintain the continued suitability and effectiveness of the QMS. Improvements can range from small continuous improvement initiatives to large ongoing strategic breakthrough improvement projects.

8.5.2 Corrective Action

General

Amphenol Alden has established and maintains documented procedures for implementing corrective and preventive action. Any corrective or preventive action taken to eliminate the cause of actual or potential non-conformities is matched appropriately to the magnitude of problems and proportionate with the risks encountered. Corrective actions are taken without undue delay. Procedures and related documents are updated as necessary to comply with changes made.

Corrective Action

Corrective actions at Amphenol Alden are handled in a timely manner, and provide for:

a.) Effective handling of customer complaints and reports of product non-conformities
b.) Investigation of the cause of non-conformities relating to product, process, quality system, and recording the results of the investigation
c.) Determination of the corrective action needed to eliminate the cause of non-conformities including, if appropriate, updating documentation
d.) Application of controls to ensure the effectiveness of the corrective action taken.
e.) Records, including the results of any investigation and of action taken.
f.) Verification that the corrective actions does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product.

8.5.3 Preventive Action

Amphenol Alden recognizes that an effective implementation of preventive action is crucial to the success of the quality system. Typical preventive action activities include:

a.) Management review of the quality system
b.) Development of quality plans
c.) Design of experiments (DOE)
d.) Failure modes and effects analysis (FMEA)

e.) Statistical process control (SPC)
f.) "Fail-safe" / "Error Proof" tools, fixtures, processes
g.) Employee suggestions for improvements to Amphenol Alden's operations

Preventive action provides for:

a.) The use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, and customer complaints, to detect, analyze and eliminate potential causes of non-conformities.
b.) Determination of the steps needed to deal with any problems requiring preventive action.
c.) Initiation of preventive action and application of controls to ensure that it is effective.
d.) Ensuring that relevant information on actions taken is submitted for management review.
e.) Immediate review of all employee suggestions for improvements
f.) Records, including the results of any investigation and of action taken.
g.) Review of action taken and its effectiveness
h.) Verification that the corrective actions does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product.

Revisions and Reference Tables for this document can be found Quality Manual Appendix