Amphenol Alden

Title:	Quality Manual
	QP 1.02.01

QUALITY MANUAL

For U.S. and Mexico Operations

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Approved:	Date:	Dept.:
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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.

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Distribution:

- This manual shall be made available on-line (read only) to all Amphenol Alden's employees
- The Quality Management System Coordinator shall maintain a signed / approved copy on file
- The General Manager and the Global Director, Quality Assurance must approve the contents of this manual and any changes
- All other paper copies shall be considered uncontrolled

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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. **Amphenol Alden does not manufacture finished medical devices; rather, Amphenol Alden designs, develops, and manufactures components to the finished medical device.** 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.

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 ISO 13485:**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 processes” identified in the Amphenol Alden Process Map in Section 4 of this manual, CRM (Customer Relationship Management) 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 / sales. 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 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 Plant 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.

1. Scope

The Amphenol Alden Quality Management System is certified to the following international standards: ISO 13485:2003. Specific requirements of ISO 13485:2003 that are not applicable to both of Amphenol Alden's operations (U.S. and Mexico) are all due to the nature of Amphenol Alden's products.

Exclusions and non Applicability:

Amphenol Alden Brockton & Hermosillo
Not applicable clause 4.2.3 section e and f Medical Device File
Justification: Amphenol Alden Products does not offer installation or servicing

Amphenol Alden Brockton & Hermosillo
Not applicable clause 4.2.5 paragraph 3 Control of Records
Justification: Amphenol Alden Products does not have records pertaining to confidential health information

Amphenol Alden Brockton & Hermosillo
Not applicable clause 6.4.2 paragraph 2 Contamination control
Justification: Amphenol Alden Products does not offer sterile products

Amphenol Alden Hermosillo Plant

Exclusion of clause 7.3 Design & Development
Justification: Brockton responsibility

Amphenol Alden Brockton & Hermosillo
Not applicable clause 7.5.2 Cleanliness of product
Justification: Amphenol Alden Products does not offer sterilization, cleanliness is controlled within QP2.09.01 Process Control

Amphenol Alden Brockton & Hermosillo
Not applicable clause **7.5.3 Installation**
Justification: Amphenol Alden products do not require installation

Not applicable clause **7.5.4 Service**
Justification: Amphenol Alden products do not require service

Not applicable clause **7.5.5 & 7.5.7 Sterilization**
Justification: Amphenol Alden products do not require sterilization

Not applicable clause **7.5.9.2 & 8.2.6 Paragraph 4 Implants**
Justification: Amphenol Alden products are not implantable

Not applicable clause 7.3.6 Paragraph 3 Design and development verification
Justification: Amphenol Alden does not make medical devices 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 **7.3.7 Paragraph 4 Design and development validation clinical evaluations** and/or evaluation of performance of the medical device, as required by national or regional regulations
Justification: Amphenol Alden does not manufacture medical devices or conduct clinical evaluations

Not applicable clause 7.3.7 Paragraph 5 Design and development validation
Justification: Amphenol Alden does not make medical devices 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 8.2.3 Reporting to regulatory authorities
Justification: Amphenol Alden 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.

Amphenol Alden's Hermosillo, Mexico is a FDA Registered Facility.

2. Normative References

International Standards ISO **13485:2016**
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 ISO 9000 and ISO 13485 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 ISO 13485:**2016**.

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: IFS reports database, 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:** QP2.01.01 Organization and Resources.

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: QP2.02.01 Quality Planning, QP 2.14.01 Corrective and Preventive Actions**.**

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.**

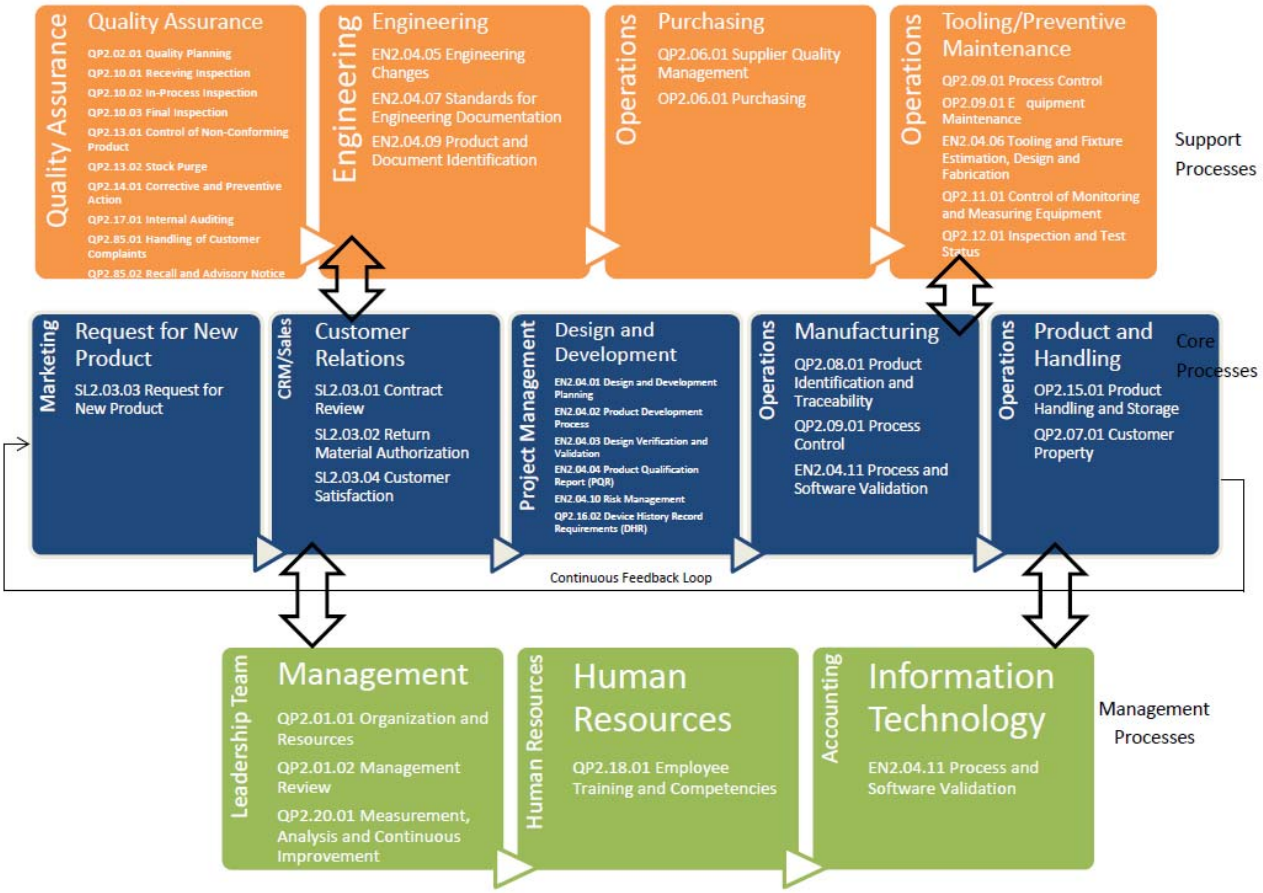
k) **Amphenol Alden ensures that changes made to the quality management systems processes are evaluated for their impact on the quality management system, evaluated for their impact on the medical devices produced under this quality management system, and are controlled in accordance with the requirements of ISO 13485:2016. Reference QP2.02.01 Quality Planning, QP2.14.01 Corrective and Preventive Actions, EN2.04.05 Engineering Changes.**

l) Amphenol Alden ensures control over outsourced processes that affect

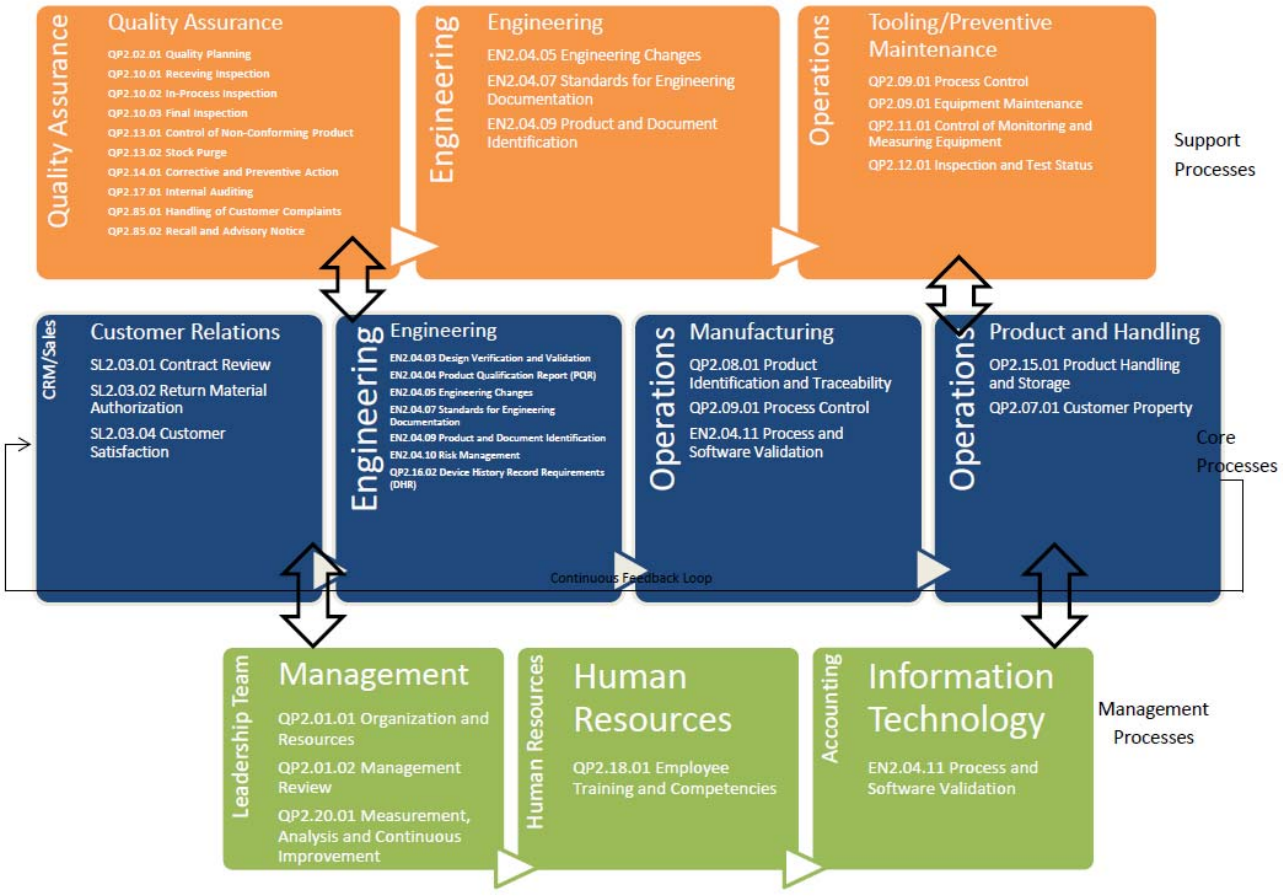
product conformity with requirements. The type and extent of control to be applied to these outsourced processes shall be defined within the Quality Management System. See Section 7.4.4 of this manual. **Reference QP2.06.01 Supplier Quality Management, OP2.06.01 Purchasing.**

m) Amphenol Alden implements validation of the application of computer software used in the quality management system. Reference EN2.04.11 Process and Software Validation.

Amphenol Alden Products Process Map (BRK)



Amphenol Alden Products Process Map (HMO)



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.

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.

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" which establish objectives in support of the corporate goals.

c.) Documented procedures and records required by ISO13485:**2016**.

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 System Documentation

Amphenol Alden has a documented quality system as described in QP2.05.01, **Document Controls.** 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):

- Drawings
- External documents such as customer supplied specifications, industry standards**,** etc. are identified and their distribution is controlled
- 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 make reference 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. This file includes, but is not limited to:

- **General description of the medical device, intended use/purpose, labelling, instructions for use. Reference EN2.04.01 Design and Development Process, EN2.04.10 Risk Management**
- **Specifications for the product or product family. Reference EN2.04.01 Design and Development Process, SL2.03.03 Request for New Product**
- **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. Reference QP2.09.01 Process Control, QP2.02.01 Quality Planning**
- **Documents defining packaging, storage, handling and distribution. Reference QP2.09.01 Process Control, OP2.15.01 Product Handling and Storage**

- **Procedures for monitoring and measuring. Reference QP2.10.01 Receiving Inspection, QP2.10.02 In-Process Inspection, QP2.10.03 Final Inspection, EN2.04.10 Risk Management**

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):

- Quality manual
- Operational procedures
- Work instructions, process procedures, and related forms
- Standards and other reference material
- Purchasing documents
- Product drawings and specifications
- 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 that in personnel, prior to issue in accordance with procedure **QP2.05.01 Document Controls**. 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

b.) Document Changes

Document changes are reviewed and approved by the same function that issued the original document, unless specifically designated otherwise. Guidelines for control of document changes are set forth in procedure **QP2.05.01 Document Controls**. Where possible, the nature of the change is identified in the document. Engineering Documents are controlled by procedure EN2.04.05 Engineering Changes. Obsolete documents are removed from use or suitably identified to prevent unintended use if retained for any purpose.

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 established 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 QP2.05.02 Good Documentation Practices. Through this procedure and in conjunction with QP2.16.01 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 collection of these records is achieved in accordance with requirements set forth in the applicable quality system procedure, and meets the requirements of procedure **QP2.16.01** Records.

The Records procedure provides for:

- Pertinent supplier quality records to be included
- 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
- Retention period for quality records to be established and recorded.
- Records are retained for a period of time at least equivalent to the life-time of the product, but no less than two years from the date of product release
- Where agreed contractually, quality records are made available for customer evaluation, for an agreed period
- Disposition of expired records (records exceeding minimum retention period)

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

Reference QP 2.01.02 Management Review, QP 2.01.01 Organization and Resources

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 both the Hermosillo Sonora, Mexico facility and the Brockton, Massachusetts facility. Amphenol Alden maintains a customer focus through continuous and effective communication with customers as described in procedure SL2.03.04 Customer Satisfaction. 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. Refer to Contract Review Procedure SL 2.03.01.

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. In accordance with procedure SL 2.03.04 Customer Satisfaction, 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 per procedure QP2.01.02 Management Review.

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 in QF2.01.02-5 Management Review Meeting Minutes.

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. Ref: QP 2.01.02 Management Review.

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 day-to-day 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 according to procedure QP 2.01.01, Organization and Resources.

5.5.2 Management Representative

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

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

- 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
- Reporting on the performance of the quality system to the General Manager and members of Top Management for review and any need for improvement
- Acting as a liaison between Amphenol Alden and external parties in matters regarding this standard
- Providing an official interpretation of Amphenol Alden's quality system
- Ensuring the promotion of awareness of **applicable** regulatory and customer requirements, **as well as Amphenol Alden's quality management system requirements** throughout the organization
- The alternate/deputy for the management representative of our organization **is designated by the Global Director of Quality.**

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. See also, QP2.01.01 Organization and Resources.

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 assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Specific details governing these reviews are included in procedure QP 2.01.02, Management Review. 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 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. Ref: QP2.01.01 Organization and Resources.

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 on the basis of appropriate education, training and/or experience, as required. Appropriate records of training are maintained per procedure QP 2.18.01 Employee Training and Competencies.

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**. Re: QP2.01.02 Management Review**, OP2.15.01 Product Handling and Storage**. 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. See OP 2.09.01, Equipment Maintenance, **QP2.09.01 Process Control, QP2.11.01 Control of Monitoring and Measuring Equipment.**

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. **Amphenol Alden has documented procedures to monitor and control the work environment, as well as monitor the health, cleanliness, and clothing of personnel. Further, when work is performed temporarily in a special environment, conditions are controlled and supervised by a competent individual.** Reference: QP2.09.01 Process Control, OP3.15.01-1 Handling and Storage of ESDS – Electrostatic Discharge Sensitive Materials.

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. Reference QP2.09.01 Process Control, QP2.13.01 Control of Non-Conforming Product, QP2.85.01 Handling of Customer Complaints.

7. Product Realization

7.1 Planning of Product Realization

(See level 2 procedures cross referenced in Appendix A)

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 executes risk management in several processes of the product realization process. Records of risk management are maintained. Reference EN2.04.02 Product Development Process, EN2.04.10 Risk Management.

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**)

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. See procedure EN2.04.10 Risk Management.

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 insure compliance to those requirements. (See SL 2.03.01 Contract Review, SL2.03.04 Customer Satisfaction)

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. Reference EN 2.04.05 Engineering Changes

7.2.3 Customer 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 (see QP2.13.01 Control of Non-Conforming Product)
e.) advisory notices (See QP2.85.02 Recall and Advisory Notice) 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. See SL2.03.01 Contract Review.

Review

Before submission of a quote, or the acceptance of a contract or order, the quote, contract or order is reviewed by Amphenol Alden, in accordance with procedure SL 2.03.01 Contract Review, to ensure that:

- 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
- Any differences between the contract or order requirements and those in the tender are resolved
- Amphenol Alden has the capability to meet the contract or order requirements

Amendment to a Contract

Contract amendments are reviewed and coordinated by Amphenol Alden according to SL 2.03.01 Contract Review procedure which identifies how an amendment to a contract is made and correctly transferred to the functions concerned within Amphenol Alden.

Records

Records of contract reviews are maintained in accordance with procedure QP 2.16.01, Records. 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 in engineering procedure EN 2.04.10 Risk Management are initiated via procedure EN2.04.02 Product Development Process and are deployed throughout the product realization process where appropriate.

7.3.2 Design and Development Planning

Amphenol Alden's Sales / Marketing Group initiates 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**

Plans are updated as the design evolves. Specific requirements for design and development planning are set forth in procedures EN2.04.01 Design and Development Planning, and EN2.04.06 Tooling and Fixture Estimation, Design, and Fabrication.

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 in accordance with procedure EN 2.04.01 Design and Development Planning.

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.** Design input requirements are governed by procedure EN2.04.01 Design and Development Planning. 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. Rules governing the design output are included in procedures EN2.04.01 Design and Development Planning, **EN2.04.02 Product Development Process**, and EN2.04.07 Standards for Engineering Documentation.

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 make reference 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. Further guidelines and records used in the design review process are defined in procedure **EN2.04.02 Product Development Process**.

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. Rules governing the design verification process are included in procedure EN2.04.03 Design Verification and Validation. **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:

- Design and process failure modes and effects analysis (FMEA)
- Modeling and simulation
- Computer aided analysis
- Performing alternative calculations
- Comparing the new design with a similar proven design, if available
- Undertaking tests and demonstrations
- Reviewing the design stage documents before release
- PQR activities in accordance with **EN2.04.04 Production Qualification Report (PQR)**

Records, results, and conclusion for design and development verification are maintained, as well as necessary actions. Further guidance on design and development verification can be found in EN2.04.03 Design Verification and Validation.

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 and is performed in accordance with EN2.04.03 Design Verification and Validation. **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.

Further guidance on design and development validation can be found in EN2.04.03 Design Verification and Validation.

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.

Further guidance on the production transfer process can be found in EN2.04.02 Product and Development Process.

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 in regards to 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. Rules governing the process for the control of design and development changes and other certain changes are included in procedure EN2.04.05 Engineering Changes. **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.

Further guidance on the production transfer process can be found in EN2.04.05 Engineering Changes & QP2.16.02 Device History Records Requirements (DHR).

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.

Evaluation and selection of suppliers

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

- **The supplier's ability to provide product that meets Amphenol Alden's requirements**
- **The performance of the supplier**

- **The effect of the purchased product on the quality of Amphenol Alden's product**
- **The proportionate risk associated with Amphenol Alden's product**

Amphenol Alden monitors and re-evaluates suppliers in accordance with QP2.06.01 Supplier Quality Management. 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. Supplier evaluation and monitoring is the joint responsibility of Purchasing and Quality Assurance.

Further guidance on the purchasing process and supplier management can be found in QP2.06.01 Supplier Quality Management and OP2.06.01 Purchasing

7.4.2 Purchasing Information

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

- The part number, revision, description, type, class, grade or other precise identification
- 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
- The title numbers and issue of the quality system standard to be applied
- 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 affect 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 EN2.04.10 Risk Management 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 in accordance with EN2.04.05 Engineering Changes.

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.

Ref QP 2.10.01 Receiving Inspection

c.) See also, section 8.2.2 Monitoring and Measuring of Product, Receiving Inspection and Testing

Records of verification are maintained in accordance with QP2.16.01 Records.

7.4.4 Control over Outsourced Processes

Amphenol Alden exercises control over outsourced processes, all product 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)
Ref: QP 3.06.01-02 Supplier Quality Manual.

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 (ref: QP2.09.01 Process Control). **Production controls** include the following:

- Procedures defining the manner of production are specified in the shop order / instruction sheets and assembly drawings prepared by the engineering department
- **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
- The availability and use of monitoring and measuring devices
- 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
- Product characteristics are monitored, **measured**, and controlled, wherever deemed necessary, through the use of process control charts
- 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
- 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
- Suitable maintenance of equipment to ensure continuing process capability is carried out in accordance with procedure OP 2.09.01, Equipment Maintenance

- The implementation of release and delivery activities
- The implementation of defined operations for labeling and packaging
- **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. Guidelines for quality planning are set forth in procedure QP 2.02.01, Quality Planning. This procedure provides for consideration to be given to the following activities, as appropriate, in meeting the specified requirements for products, projects or contracts:

- The preparation of quality plans
- 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
- Ensuring the compatibility of the design, the production process, inspection and test procedures and the applicable documentation
- The updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation
- 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
- The identification of suitable verification at appropriate stages in the realization of product
- The clarification of standards of acceptability for all features and requirements, including those which contain a subjective element
- The identification and preparation of quality records
- 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 Validation of Processes for Production and Service Provision

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

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 as a consequence 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
d.) requirements for records
e.) revalidation, **including criteria for revalidation**
f.) approval of changes to the processes

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.

See procedure EN 2.04.11 Process and Software Validation**.**

7.5.3 Identification

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. Procedure EN 2.04.09 Product and Document Identification covers assignment of part numbers. Procedure QP 2.08.01, Product Identification and Traceability covers maintenance of product identification and traceability as it is stored or moved throughout the facility.

Status Identification:
Product is identified throughout product realization and subsequent storage to insure 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.

7.5.4 Traceability

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.

7.5.5 Customer Property

Amphenol Alden has established and maintains documented procedures for the control of verification, storage 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. Procedure QP 2.07.01, Customer Property, contains further instructions,

and references applicable procedures governing the handling, verification, marking, storage and disposition of customer supplied product.

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

7.5.6 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: OP 2.15.01, Product Handling and Storage.

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 included in procedure OP 2.15.01, Product Handling and Storage.

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 identified in procedure OP 2.15.01 Product Handling and Storage. 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. Packaging and marking activities are governed by procedure OP 2.15.01 Product Handling and Storage.

Preservation

Appropriate methods for preservation and segregation of product are applied as necessary, in accordance with procedure OP 2.15.01 Product Handling and Storage.

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. Guidelines for product delivery are included in procedure OP 2.15.01 Product Handling and Storage. 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. Receiving Inspection will clearly mark the expiration date on the product using “Do Not Use After” labels (unless it is readily apparent by manufacturer’s labeling). Product which is found to exceed its shelf life will be discarded as described in OP 2.15.01 Product Handling and Storage.

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 by Amphenol Alden to demonstrate the conformance of product to the specified requirements. Calibration methods will be traceable to NIST (US), or international country equivalent (Mexico), 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:

- **Calibrated or verified, or both, at specified intervals or prior to use traceable to NIST (US), or international country equivalent (Mexico).**
- **Adjusted or re-adjusted as necessary. Adjustments or re-adjustments are recorded.**
- **Identified with its calibration status**
- **Safeguarded from adjustments that would invalidate the measurement results**
- **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 with 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 in procedure QP2.11.01 Control of Monitoring and Measuring Equipment.

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**

QP 2.20.01 Measurement, Analysis and Continuous Improvement describes how Amphenol Alden determines, collects, and analyzes appropriate data on a regular basis to demonstrate the suitability and effectiveness of the QMS, and to demonstrate continuous improvement.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction / 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 within procedures QP2.14.01 Corrective and Preventive Action 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,** QP2.20.01 Measurement, Analysis and Continuous Improvement, QP2.17.01 Internal Auditing, and SL2.03.04 Customer Satisfaction, and QP2.85.01 Handling of Customer Complaints.

8.2.2 Complaint Handling

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

- **Receiving and recording information**
- **Evaluating information to determine if the feedback constitutes a complaint**
- **Investigating complaints**

- **Determining the need to report the information to the appropriate customers (QP2.85.02 Recall and Advisory Notice)**
- **Handling of complaint related product**
- **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 in accordance with QP2.06.01 Supplier Quality Management.

Further information on the complaint handling process can be found in QP2.85.01 Handling of Customer Complaints.

8.2.3 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 is contained in procedure QP2.17.01, Internal Auditing.

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. **Reference QP2.14.01 Corrective and Preventive Action.**

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

8.2.4 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:

- External PPM
- Scrap
- Sales
- On time delivery
- 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.

8.2.5 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.

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. Details relating to inspection and test status are set forth in procedures QP 2.12.01 Inspection and Test Status and QP 2.08.01 Product Identification and Traceability.

Receiving Inspection and Testing

- Amphenol Alden ensures that incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements. This is accomplished by adhering to requirements set forth in procedure QP 2.10.01 Receiving Inspection. 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.

- 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. This is accomplished through a focus on continued supplier improvement, and execution of the guidelines set forth in procedure QP 2.10.02, Supplier Quality Management.

In-process Inspection and Testing

- In-process inspection and test of product is performed as required by the quality plan and guidelines set forth in procedure QP 2.10.02, In-process Inspection. This procedure provides guidelines for both first piece and in-process inspection. **Test equipment used to perform measurement activities is identified.**
- In-process inspection procedure provides guidelines for holding product until the required tests have been completed.

Final Inspection and Testing

- Final inspection and test is carried out in accordance with the procedure QP 2.10.03, Final Inspection, and applicable inspection plan to complete the evidence of conformance of the finished product to the specified requirements.

- 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.**

- 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" tag 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. Rules for establishing and maintaining these records are described in procedures QP 2.10.01 Receiving Inspection, QP 2.10.02 In-process Inspection and QP 2.10.03 Final Inspection. 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.** Filing and maintenance of inspection records is regulated by procedure QP 2.16.01, Records. Where product fails to pass any inspection and/or test, it is handled in accordance with procedure QP 2.13.01, Control of Non-Conforming Product.

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 regards to the need for an investigation and notification of any external party responsible for the non-**

conformity. Notification of external parties shall be done in accordance with QP2.06.01 Supplier Quality Management.

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 defined in procedure QP 2.13.01 Control of Non-Conforming Product. Non-conforming product is reviewed in accordance with this procedure and may be dispositioned as follows:

- Accept as is
- Rework
- Scrap **(precluding its intended use or application)**
- 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:
- Trends
- Customer Satisfaction/Feedback
- Conformity to product requirements
- Effectiveness and efficiency of the processes
- Supplier Quality
- **Audits**
- Overall Plant Performance
- Conformity and effectiveness of the QMS
- 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: QP2.20.01 Measurement Analysis and Continuous Improvement, QP2.01.02 Management Review.

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, in accordance with procedure QP2.14.01 Corrective and Preventive Action. This procedure provides for:

- Effective handling of customer complaints and reports of product non-conformities
- Investigation of the cause of non-conformities relating to product, process, quality system, and recording the results of the investigation
- Determination of the corrective action needed to eliminate the cause of non-conformities including, if appropriate, updating documentation
- Application of controls to ensure the effectiveness of the corrective action taken
- Records, including the results of any investigation and of action taken
- **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:

- Management review of the quality system
- Development of quality plans
- Design of experiments

- Failure modes and effects analysis (FMEA)
- Statistical process control (SPC)
- "Fail-safe" tools, fixtures, processes
- Employee suggestions for improvements to Amphenol Alden's operations

Preventive action is carried out in accordance with procedure QP2.14.01 Corrective and Preventive Action, which provides for:

- 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
- Determination of the steps needed to deal with any problems requiring preventive action
- Initiation of preventive action and application of controls to ensure that it is effective
- Ensuring that relevant information on actions taken is submitted for management review
- Immediate review of all employee suggestions for improvements
- Records, including the results of any investigation and of action taken
- Review of action taken and its effectiveness
- **Verification that the corrective actions does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product**

Document Change Record

REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
T	6 July 2015	Maeghan Thomas	Section 1. Scope	Not applicable clause 7.3.6 Design and development validation clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (including Note 1 and Note 2) Justification: Amphenol Alden does not manufacture medical devices or conduct clinical evaluations
U	15 June 2016	Mary Horgan	Distribution	Changed "Corporate Quality Assurance Manager" to "Global Director, Quality Assurance"
			Section 1, Scope	Updated ISO13485 to ISO13485:2003

Document Change Record

REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
			Section 4.1 (f), (g) Section 4.2.1, Section 4.2.2 Section 7.2.2 Section 7.3.1 Section 7.5, 2nd bullet Section 7.5.2 Section 8.2.2, Receiving Inspection and Testing, 1st bullet Section 8.2.2, Receiving Inspection and Testing, 2nd bullet Section 8.5.1 Appendix A, ISO 4.1 par d Appendix A, ISO 4.1 par e Appendix A, ISO 4.2.3 par b	Grammatical and spelling corrections
			Section 4.2.3 (a)	Added guidance “or controlled access to hard copies when electronic version is not available”
			Section 5.4.1	Replaced “our Meeting Minutes Form QF 2.01.02-1” with “QF2.01.02-5 Management Review Meeting Minutes”.
			Section 5.5.2	Replaced “the Senior Staff” with “Top Management”
			Section 5.5.3	Added “an”
			Section 6.2.2	Corrected procedure title to “Employee Training and Competencies”
			Section 7.2	Corrected procedure title to “Contract Review”
			Section 7.3.1 (c)	Corrected procedure title to “Tooling and Fixture Estimation, Design, and Fabrication”
			Section 7.3.1	Corrected procedure title to “Design and Development Planning”
			Section 7.3.7	Added guidance “and other certain changes”
			Section 7.4.3 (c)	Corrected section reference to “8.2.2 Monitoring and Measuring of Product, Receiving Inspection and Testing”
			Section 8.2.2	Removed “see 13.2”
			Section 8.2.2, Inspection and Test Records	Added procedure title “Receiving Inspection” Added procedure title “In-process Inspection” Added procedure title “Final Inspection”
			Section 8.3, Review and Disposition of Non-Conforming Product	Added guidance “or as per customer agreements”
			Appendix A, 4.1 ISO par c	Corrected procedure title “Corrective and Preventive Action”
			Appendix A, 4.1 ISO par d	Corrected procedure title “Employee Training and Competencies”
			Appendix A, 4.2.2 ISO par a	Removed “Page 4”
			Appendix A, 4.2.2 ISO par c	Removed “Page 5” Changed “Core Process Interaction Chart” to “Amphenol Alden Products Process Map”
			Appendix A, 5.1 ISO par a	Changed paragraph reference to 7.2.4
			Appendix A, 5.1 ISO par b	Changed paragraph reference to 7.2.5
			Appendix A, 5.1 ISO par c	Changed paragraph reference to 7.2.7

Document Change Record

REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
			Appendix A, 5.1 ISO par e	Changed paragraph reference to 7.1.2
			Appendix A, 5.3 ISO par a	Changed paragraph reference to 7.2.5
			Appendix A, 5.4.1	Changed paragraph reference to 6.1
			Appendix A, 5.4.2 ISO par a	Corrected form title to "Management Review Requirements Form"
			Appendix A, 5.5.3	Changed paragraph reference to 7.2.4
			Appendix A, 5.6.1	Changed paragraph reference to 7.1.3
			Appendix A, 6.1 ISO par a	Changed paragraph reference to 7.1.2
			Appendix A, 6.2.2	Removed "add 'identification of training needs'"
			Appendix A, 6.3	Replaced "item 9" with "item 10"
			Appendix A, 6.4	Replaced "item 7" with "item 8" Changed paragraph reference to 7.7
			Appendix A, 7.5.1.1 ISO par g	Added paragraph reference 7.3
			Appendix A, 7.5.1.2.1 ISO par a-d	Changed paragraph reference to 7.4.1, 7.4.6
			Appendix A., 7.5.3.3	Removed "revise level 2 to add use of tags for all test product"
			Appendix A, 7.6	Corrected procedure title to "Control of Monitoring and Measuring Equipment"
			Appendix A, 8.2.1	• Changed paragraph reference to 6.1.1
			Appendix B	Removed procedure reference SL2.03.05 Cable Product Development Process Added HMO site application for EN2.04.04 Product Qualification Report (PQR) Corrected procedure title to "Process and Software Validation" Corrected procedure title to "Control of Monitoring and Measuring Equipment" Corrected procedure title to "Stock Purge" Corrected procedure title to "Employee Training and Competencies"
V	30 March 2017	Mary Horgan	Appendix B	Added "QP2.05.02 Good Documentation Practices" Added "QP2.16.02 Device History Record Requirements"
W	**07 September 2018**	**Mary Horgan**	**All** **Section 0, General** **Process Approach** **Section 1, Scope**	**Changed reference from ISO13485:2006 to ISO13485:2016 & removed reference to ISO9001:2008** **Added "and manufacture"** **Added "Original Equipment Manufacturer (OEM)"** **Added "Amphenol Alden does not manufacture finished medical devices; rather, Amphenol Alden designs, develops, and manufactures components to the finished medical device."** **Added "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."** **Added and edited "Amphenol Alden Brockton & Hermosillo** **Not applicable clause 4.2.3 section e and f Medical Device File** **Justification: Amphenol Alden Products does not offer installation or servicing** **Added "Amphenol Alden Brockton & Hermosillo** **Not applicable clause 4.2.5 paragraph 3 Control of Records** **Justification: Amphenol Alden Products does not have records pertaining to confidential health information"** **Amphenol Alden Brockton & Hermosillo**

Document Change Record

REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
				Not applicable clause 6.4.2 paragraph 2 Contamination control **Justification: Amphenol Alden Products does not offer sterile products"** **Added and edited "Amphenol Alden Brockton & Hermosillo** **Not applicable clause 7.5.2 Cleanliness of product** **Justification: Amphenol Alden Products does not offer sterilization, cleanliness is controlled within QP2.09.01 Process Control"** **Added and edited "Amphenol Alden Brockton & Hermosillo** **Not applicable clause 7.5.3 Installation** **Justification: Amphenol Alden products do not require installation"** **Added and edited "Not applicable clause 7.5.4 Service** **Justification: Amphenol Alden products do not require service"** **Added and edited "Not applicable clause 7.5.5 & 7.5.7 Sterilization** **Justification: Amphenol Alden products do not require sterilization"** **Added and edited "Not applicable clause 7.5.9.2 & 8.2.6 Paragraph 4 Implants** **Justification: Amphenol Alden products are not implantable"** **Added "Not applicable clause 7.3.6 Paragraph 3 Design and development verification** **Justification: Amphenol Alden does not make medical devices and does not verify the design outputs against the design inputs of a medical device when connected or interfacing with another device"** **Added "7.3.7 Paragraph 4 Design and development validation clinical evaluations"** **Added "Not applicable clause 7.3.7 Paragraph 5 Design and development validation** **Justification: Amphenol Alden does not make medical devices 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 8.2.3 Reporting to regulatory authorities** **Justification: Amphenol Alden does not directly report to regulatory authorities, it is done through our customers"** **Added "Amphenol Alden's Hermosillo, Mexico is a FDA Registered Facility.**
			Section 2 **4.1 General**	**Added and edited "International Standards ISO 13485:2016"** **Added "a) Amphenol Alden establishes, implements, and maintains any requirement, procedure, activity or arrangement required to be documented."** **Added "b) Amphenol Alden has taken the role of the manufacturer with the responsibility for the design and/or manufacture of a medical device."** **Added "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)"** **Added "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."** **Added "k) Amphenol Alden ensures that changes made to the quality management systems processes are evaluated for their**

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				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 QP2.02.01 Quality Planning, QP2.14.01 Corrective and Preventive Actions, EN2.04.05 Engineering Changes." **Added " Reference QP2.06.01 Supplier Quality Management, OP2.06.01 Purchasing." To section L** **Added "m) Amphenol Alden implements validation of the application of computer software used in the quality management system. Reference EN2.04.11 Process and Software Validation."** **Created new process maps for HMO and BRK**
			Section 4.2.2	**Changed Quality Systems Documentation to Document Controls**
			Section 4.2.3	**Added "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. This file includes, but is not limited to:** **•General description of the medical device, intended use/purpose, labelling, instructions for use. Reference EN2.04.01 Design and Development Process, EN2.04.10 Risk Management** **•Specifications for the product or product family. Reference EN2.04.01 Design and Development Process, SL2.03.03 Request for New Product** **•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. Reference QP2.09.01 Process Control, QP2.02.01 Quality Planning** **•Documents defining packaging, storage, handling and distribution. Reference QP2.09.01 Process Control, OP2.15.01 Product Handling and Storage** **•Procedures for monitoring and measuring. Reference QP2.10.01 Receiving Inspection, QP2.10.02 In-Process Inspection, QP2.10.03 Final Inspection, EN2.04.10 Risk Management"**
			Section 4.2.4	**Fixed numbering** **Changed "Quality System Documentation" Document Controls"**
			Section 4.2.5	**Fixed numbering** **Added "security and integrity"** **Added "Changes to quality records are performed in accordance with QP2.05.02 Good Documentation Practices. Through this procedure and in conjunction with QP2.16.01 Records, Amphenol Alden ensures that quality records remain legible, readily identifiable, and readily retrievable.**
			Section 5.1	**Added "applicable" to item a**
			Section 5.2.1	**Added "requirements and applicable regulatory requirements"**
			Section 5.4.1	**Added "meet applicable regulatory requirements as well as"**
			Section 5.5.2	**Added "processes for Amphenol Alden's" and "of applicable regulatory and customer requirements, as well as Amphenol Alden's quality management system requirements throughout the organization"**

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REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
				Changed "are the Global Operations Director and/or Plant Manager for our Brockton and Hermosillo Mexico facilities, respectively" to "is designated by the Global Director of Quality."
			Section 5.6	**Corrected formatting**
			Section 6.1	**Added "applicable"**
			Section 6.2	**Removed "6.2.1 & 6.2.2"** **Added and edited "maintained for establishing competence, identifying training needs and provide for training of all personnel performing activities affecting quality and ensuring awareness of personnel."**
			Section 6.3	**Added "preventing mix-ups, and ensuring orderly handling of product."** **Added "OP2.15.01 Product Handling and Storage."** **Added "The requirements shall apply to equipment used in production, the control of the work environment and monitoring and measuring as appropriate."** **Added "QP2.09.01 Process Control, QP2.11.01 Control of Monitoring and Measuring Equipment."**
			Section 6.4	**Added "Contamination Control"**
			Section 6.4.1	**Added "Amphenol Alden has documented procedures to monitor and control the work environment, as well as monitor the health, cleanliness, and clothing of personnel. Further, when work is performed temporarily in a special environment, conditions are controlled and supervised by a competent individual."**
			Section 6.4.2	**Added "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. Reference QP2.09.01 Process Control, QP2.13.01 Control of Non-Conforming Product, QP2.85.01 Handling of Customer Complaints."**
			Section 7.1	**Added "Amphenol Alden executes risk management in several processes of the product realization process. Records of risk management are maintained. Reference EN2.04.02 Product Development Process, EN2.04.10 Risk Management."** **Added "Including infrastructure and work environment."** **Added "handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance"**
			Section 7.2.1	**Added "post-delivery activities"** **Added "applicable" & "related"**
			Section 7.2.2	**Added "applicable regulatory requirements are met"**
			Section 7.2.3	**Added "e) advisory notices (See QP2.85.02 Recall and Advisory Notice) 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."**
			Section 7.3.1	**Reformatted section** **Changed "EN2.04.02 Design Review" to EN2.04.02 Product Development Process"**
			Section 7.3.2	**Add and reformatted "b.) The reviews needed at each design and development stage"**

Document Change Record

REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
				Add and reformatted "c.) The verification, validation and design transfer activities (see note below) that are appropriate at each design and development stage" **Add and reformatted "e.) The methods to ensure traceability of the design and development outputs to the design and development inputs"** **Add and reformatted "f.) Resources needed, including necessary competence of personnel"**
			Section 7.3.3	**Added "Amphenol Alden ensures that all incomplete, ambiguous, conflicting, or unverifiable or invalid requirements are resolved with the customer."**
			Section 7.3.4	**Changed "EN2.04.02 Design Review" to EN2.04.02 Product Development Process"** **Added "and development"** **Added "safety"**
			Section 7.3.5	**Added "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. Further guidelines and records used in the design review process are defined in procedure EN2.04.02 Product Development Process."**
			Section 7.3.6	**Added "Verification plans are documented and include methods, acceptance criteria, and as appropriate, statistical techniques with rationale for sample size."** **Added "PQR activities in accordance with EN2.04.04 Production Qualification Report (PQR)"** **Added "Records, results, and conclusion for design and development verification are maintained, as well as necessary actions. Further guidance on design and development verification can be found in EN2.04.03 Design Verification and Validation."**
			Section 7.3.7	**Added "and documented"** **Added "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."** **Added "Further guidance on design and development validation can be found in EN2.04.03 Design Verification and Validation."**
			Section 7.3.8	**New section**
			Section 7.3.9	**Added "Added "Amphenol Alden has procedures and processes to control design and development changes. Amphenol Alden determines the significance of the change in regards to function, performance, usability, safety and applicable regulatory requirements for the product and its intended use."** **Added "as well as the inputs or outputs of the risk management and product realization process."** **Added "Records of their changes, review and any necessary actions are records and maintained."**
			Section 7.3.10	**New section**
			Section 7.4.1	**Rewrote entire section**

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REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
			Section 7.4.2	**Added "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 affect the ability of the purchased product to meet specified purchasing requirements."**
			Section 7.4.3	**Added "Records of verification are maintained in accordance with QP2.16.01 Records."** **Added "Verification activities are done in accordance with EN2.04.10 Risk Management and are proportionate to the risks associated with the purchased product."** **Added "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 in accordance with EN2.04.05 Engineering Changes."**
			Section 7.5	**Changed "Controlled conditions" to "Production controls"** **Added "Availability and use of suitable production equipment" instead of "Use of suitable production equipment"** **Added "measuring" to two bullet points** **Added "Appropriate qualification of infrastructure"**
			Section 7.5.1	**Renumbered section**
			Section 7.5.2	**Added "and acceptance of criteria"** **Added 'statistical techniques with rationale for sample size as appropriate"** **Added" including criteria for revalidation"** **Added "approval of changes to the processes"** **Added "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."**
			Section 7.5.3	**Renumbered section, split old section 7.5.3**
			Section 7.5.4	**Renumbered section, split old section 7.5.3**
			Section 7.5.5	**Renumbered section**
			Section 7.5.6	**Renumbered section** **Added "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."**
			Section 7.6	**Added "Amphenol Alden ensures that measuring equipment is:** **•Calibrated or verified, or both, at specified intervals or prior to use traceable to NIST (US), or international country equivalent (Mexico).** **•Adjusted or re-adjusted as necessary. Adjustments or re-adjustments are recorded.** **•Identified with its calibration status**

Document Change Record

REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
				•Safeguarded from adjustments that would invalidate the measurement results •Protected against damage and deterioration during handling, maintenance and storage. Added "In the event that equipment is found not to conform with requirements, Amphenol Alden performs an assessment and records the validity of previous measurements." Added "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."
			Section 8.1	Changed "maintain the effectiveness of the QMS as required by ISO 13485:2003 and to identify areas for continuous improvement as required by ISO 9001:2008" to ensure conformity and maintain effectiveness to the QMS as required by ISO13485:2016" Removed "c) To ensure a high degree of customer satisfaction"
			Section 8.2.1	Added "from production to post-production activities" Added" risk management for monitoring and measuring product requirements" Added "the product realization process and improvement processes"
			Section 8.2.2	New section
			Section 8.2.3	Renumbered section Added "Reference: QP2.14.01 Corrective and Preventive Action"
			Section 8.2.4	Renumbered section
			Section 8.2.5	Renumbered section
			Section 8.2.5 Receiving Inspection and Testing	Added "test equipment used to perform measurement activities is identified"
			Section 8.2.5 In-process Inspection and Testing	Added "Test equipment used to perform measurement activities is identified."
			Section 8.2.5 Final Inspection and Testing	Added "Test equipment used to perform measurement activities is identified."
			Section 8.2.5 Inspection and Test Records	Added "test equipment used to perform measurement activities is identified"
			Section 8.3.1	Added "When evaluating the non-conformity, an evaluation shall be made in regards to the need for an investigation and notification of any external party responsible for the non-conformity. Notification of external parties shall be done in accordance with QP2.06.01 Supplier Quality Management."
			Section 8.3.2	New section, split content from 8.3 Added "precluding its intended use or application"

Document Change Record				
REVISION NO.	DATE	BY	SECTION / PARAGRAPH REFERENCE	CHANGE SUMMARY
				Added "If product is accepted as is, Amphenol Alden provides justification of such concession including the person or personnel authorizing the concession."
			Section 8.3.3	**New section, split content from 8.3**
			Section 8.3.4	**New section, split content from 8.3**
			Section 8.4	**Added "- Audits"**
				Added "If the analysis of data shows that the QMS is not suitable, adequate or effective, this shall be an input to improvement activities."
			Section 8.5.1	**Added "post market surveillance (feedback)"**
				Added and edited "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."
			Section 8.5.2	**Added "Corrective actions are taken without undue delay."**
				Added " Verification that the corrective actions does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product"
			Section 8.5.3	**Added "Verification that the corrective actions does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product"**
			Appendix A	**Revised to align with IS13485:2016 standard**
			Appendix B	**Added HMO application to SL2.03.01 Contract Review and SL2.03.04 Customer Satisfaction**
				Removed HMO application from QP2.06.01 Supplier Quality Management

APPENDIX A:

CROSS-REFERENCE: **ISO13485:2016** to Amphenol Alden Procedures

ISO 13485:20**16** sect.	ISO par	Amphenol Alden Products QMS Reference
4 Quality management system		
4.1 General requirements		
4.1.1		**QP 1.02.01 Quality Manual - Introduction and Scope**
4.1.2	**a.)**	**QP 1.02.01 Quality Manual – Amphenol Alden Process Map**
	b.)	**EN2.04.10 Risk Management**
	c.)	**QP 1.02.01 Quality Manual – Amphenol Alden Process Map**
4.1.3	**a.)**	**QP 2.01.02 Management Review**

ISO 13485:20**16** sect.	ISO par	Amphenol Alden Products QMS Reference
		QP 2.14.01 Corrective and Preventive Action **QP 2.17.01 Internal Auditing**
	b.)	**QP 2.01.02 Management Review** **QP 2.01.01 Organization and Resources** **QP 2.18.01 Employee Training and Competencies**
	c.)	**QP 2.01.02 Management Review**
	d.)	**QP 2.01.02 Management Review** **QP 2.20.01 Measurement, Analysis and Continuous Improvement**
4.1.3	**e.)**	**QP 2.16.01 Records**
4.1.4	**a.)**	**QP2.05.01 Document Control**
	b.)	**EN2.04.05 Engineering Changes** **QP2.14.01 Corrective and Preventive Action**
	c.)	**QP2.05.01 Document Control**
4.1.5		**QP2.06.01 Supplier Quality Management** **OP2.06.01 Purchasing**
4.1.6		**EN2.04.11 Process and Software Validation**
4.2 Documentation requirements		
4.2.1 General	a.)	QP 1.02.01 Quality Manual
	b.)	QP 1.02.01 Quality Manual
	c-d.)	Amphenol Alden QMS – all procedures
	e.)	**QP 2.16.01 Records** **Amphenol Alden QMS – all procedures**
4.2.2 Quality Manual	a.)	Introduction and Scope
	b.)	all sections
	c.)	Amphenol Alden Products Process Map
4.2.3 Medical Device File	**a-d.)**	**QP2.16.02 Device History Records Requirements (DHR)**
4.2.4 Control of Documents	**a.)**	**QP 2.05.01 Document Control**
	b.)	**QP 2.05.01 Document Control** **QP 2.17.01 Internal Auditing**
	c.)	**QP 2.05.01 Document Control**
	d-g.)	**All documents are controlled electronically and are available on-line**
4.2.5 Control of Records		**QP 2.16.01 Records**

5 Management responsibility		
5.1 Management commitment	a.)	**QP 2.01.02 Management Review**
	b.)	**QP 2.01.02 Management Review**
	c.)	**QP 2.01.02 Management Review**

	d.)	**QP 2.01.02 Management Review**
	e.)	**QP 2.01.01 Organization and Resources**
5.2 Customer Focus		**QP 2.01.02 Management Review**
5.3 Quality policy	a.)	**QP 2.01.02 Management Review**
	b.)	**QP 2.01.02 Management Review**
	c-e.)	**QP 2.01.02 Management Review**
5.4 Planning		
5.4.1 Quality Objectives		**QP 2.01.02 Management Review**
5.4.2 Quality management system planning	a.)	Form: QF 2.01.02-2 Management Review Requirements Form
	b.)	QP 2.01.02 Management Review **QP 2.05.01 Document Control** QP 2.17.01 Internal Auditing
5.5 Responsibility and authority		
5.5.1 Responsibility and authority		**QP 2.01.01 Organization & Resources** **QP 2.01.01 Management Review**
5.5.2 Management representative	a-c.)	**QP 2.01.01 Organization and Resources**
5.5.3 Internal Communication		**QP 2.01.02 Management Review**
5.6 Management review		
5.6.1 General		QP 2.01.02 **Management Review**
5.6.2 Review Input	**a.)- l.)**	QP 2.01.02 **Management Review**
5.6.3 Review Output	**a.)-d.)**	QP 2.01.02 **Management Review**
6 Resource management		
6.1 Provision of resources	a.) **& b.)**	QP2.01.01 **Organization and Resources**
6.2 Human resources		**QP2.01.01 Organization and Resources** **QP2.18.01 Employee Training and Competencies**
6.3 Infrastructure	a.)-c.)	**QP 2.02.01 Quality Planning** **OP2.09.01 Equipment Maintenance** **OP2.15.01 Product Handling and Storage**
6.4.1 Work environment		**QP 2.02.01 Quality Planning** **QP 2.09.01 Process Control** **OP3.15.01-1 Handling and Storage of ESDS – Electrostatic Discharge Sensitive Materials**
	a-b.)	N/A – due to the nature of our products, special environmental requirements are rare, however in cases where there are specific environmental requirements, they are documented within the individual product assembly work instructions.

6.4.2 Contamination control		**QP2.09.01 Process Control** **QP2.13.01 Control of Non-Conforming Product** **QP2.85.01 Handling of Customer Complaints**
		Note: Amphenol Alden does not supply sterile medical devices
7 Product Realization		
7.1 Planning of product realization		**QP2.02.01 Quality Planning** **SL2.03.01Contract Review** **SL2.03.03 Request for New Product** **EN2.04.02 Product Development Process** **EN2.04.10 Risk Management**
7.2 Customer-related processes		
7.2.1 Determination of requirements related to product		SL2.03.01 Contract Review **EN2.04.01 Design and Development Planning**
7.2.2 Review of requirements related to the product		SL2.03.01 Contract Review **EN2.04.01 Design and Development Planning**
7.2.3 Customer communication	a-c.)	SL2.03.01 Contract Review SL2.03.04 Customer Satisfaction
	d.)	N/A – Note: advisory notices are the responsibility of Amphenol Alden's customers/medical device manufacturers. **See 8.2.3.**
7.3 Design and development		
7.3.1 General		**EN2.04.01 Design and Development Planning** **EN2.04.02 Product Development Process**
7.3.2 Design and Development Planning		EN2.04.01 Design and Development Planning **EN2.04.02 Product Development Process**
7.3.3 Design and development inputs		EN2.04.01 Design and Development Planning
7.3.4 Design and development outputs		EN2.04.01 Design and Development Planning
7.3.5 Design and development review		**EN2.04.02 Product Development Process**
7.3.6 Design and development verification		EN2.04.03 Design Verification and Validation EN2.04.04 Product Qualification Report (PQR)
7.3.7 Design and development validation		EN2.04.03 Design Verification and Validation Note: Clinical evaluations are performed by the instrument manufacturer (Amphenol Alden's customers)
7.3.8 Design and development transfer		**EN2.04.02 Product Development Process**
7.3.9 Control of design and development changes		EN2.04.05 Engineering Changes

7.3.10 Design and development files		**QP2.16.02 Device History Record Requirements (DHR)**
7.4 Purchasing		
7.4.1 Purchasing process	**a-d.)**	OP2.06.01 Purchasing QP2.06.01 Supplier Quality Management
7.4.2 Purchasing information	**a-d.)**	OP2.06.01 Purchasing **QP2.06.01 Supplier Quality Management**
7.4.3 Verification of purchased product		QP2.10.01 Receiving Inspection **QP2.06.01 Supplier Quality Management**
7.5 Production and service provision		
7.5.1 Control of production and service provision	**a.)**	**QP2.09.01 Process Control**
	b.)	**QP2.09.01 Process Control**
	c.)	**QP 2.09.01 Process Control** **QP 2.20.01 Measurement, Analysis and Continuous Improvement**
	d.)	**QP 2.10.01 Receiving Inspection** **QP2.10.02 In-Process Inspection** **QP2.10.03 Final Inspection** **QP 2.11.01 Control of Monitoring and Measuring Equipment**
	e.)	**QP2.15.01 Product Handling and Storage**
	f.)	**QP 2.10.03 Final Inspection** **OP2.15.01 Product Handling and Storage**
7.5.2 Cleanliness of Product	**a–e.)**	**QP2.09.01 Process Control– Note: Amphenol Alden does not offer sterilization of product to any of its customers. Specific cleanliness requirements that may be specified by customers over and above basic workmanship are defined in the individual part assembly work instructions (level 3).**
7.5.3 Installation activities		N/A
7.5.4 Servicing activities		N/A
7.5.5 Particular requirements for sterile medical devices		N/A
7.5.6 Validation of processes for production and service provision	**a-g.)**	**EN2.04.11 Process and Software Validation**
7.5.7 Particular requirements for validation of processes for sterilization and sterile medical devices		**N/A**

7.5.8 Identification		QP 2.08.01 Product Identification and Traceability QP 2.12.01 Inspection and Test Status QP 2.13.01 Control of Non-Conforming Product
7.5.9 Traceability		
7.5.9.1 General		QP 2.08.01 Product Identification and Traceability QP 2.12.01 Inspection and Test Status
7.5.9.2 Particular requirements for implantable medical devices		N/A
7.5.10 Customer property		QP 2.07.01 Customer Property
7.**5.11 Preservation of product**		QP 2.15.01 Product Handling and Storage
7.6 Control of monitoring and measuring devices		QP 2.11.01 Control of Monitoring and Measuring Equipment **EN2.04.11 Process and Software Validation**
8 Measurement, analysis and improvement		
8.1 General	a.)-c.)	QP 2.01.02 Management Review QP 2.20.01 Measurement, Analysis and Continuous Improvement
8.2 Monitoring and Measurement		
8.2.1 Feedback / Customer satisfaction		QP 2.01.02 Management Review SL 2.03.01 Contract Review SL 2.03.04 Customer Satisfaction QP 2.14.01 Corrective and Preventive Action QP2.85.01 Handling of Customer Complaints
8.2.2 Complaint Handling		**QP 2.14.01 Corrective and Preventive Action** **QP2.85.01 Handling of Customer Complaints**
8.2.3 Reporting to Regulatory Authorities		**N/A**
8.2.**4** Internal Audit		QP 2.17.01 Internal Auditing
8.2.**5** Monitoring and measurement of processes		QP 2.01.02 Management Review QP 2.09.01 Process Control QP 2.17.01 Internal Auditing QP 2.20.01 Measurement, Analysis and Continuous Improvement
8.2.4 Monitoring and measurement of product		**QP 2.02.01 Quality Planning** **QP 2.10.01 Receiving Inspection** **QP 2.10.02 In-Process Inspection** **QP 2.10.03 Final Inspection** **QP 2.20.01 Measurement, Analysis and Continuous Improvement**
8.3 Control of Nonconforming		**QP 2.13.01 Control of Non-Conforming Product**

product		
8.3.1 General		**QP 2.13.01 Control of Non-Conforming Product**
8.3.2 Actions in response to non-conforming product detected before delivery		**QP 2.13.01 Control of Non-Conforming Product** **QP2.14.01 Corrective and Preventive Action**
8.3.3 Actions in response to non-conforming product detected after delivery		**QP 2.13.01 Control of Non-Conforming Product** **QP2.14.01 Corrective and Preventive Action** **QP2.85.01 Handling of Customer Complaints** **QP2.85.02 Recall and Advisory Notices**
8.3.4 Rework		**QP 2.13.01 Control of Non-Conforming Product**
8.4 Analysis of data		QP 2.01.02 Management Review QP 2.14.01 Corrective and Preventive Action QP 2.20.01 Measurement, Analysis and Continuous Improvement
8.5 Improvement		
8.5.1 General		**QP 2.01.02 Management Review** **QP 2.14.01 Corrective and Preventive Action** **QP 2.20.01 Measurement, Analysis and Continuous Improvement**
8.5.2 Corrective action		QP 2.14.01 Corrective and Preventive Action
8.5.3 Preventive action		QP 2.14.01 Corrective and Preventive Action

APPENDIX B:

Index of Level II Procedures **SITE APPLICATION**

Procedure title	Procedure title	BRK	HMO
QP 2.01.01	Organization and Resources	X	X
QP 2.01.02	Management Review	X	X
QP 2.02.01	Quality Planning	X	X
SL 2.03.01	**Contract Review**	**X**	**X**
SL 2.03.02	Return Material Authorization	X	X
SL 2.03.03	Request For New Product	X	
SL 2.03.04	**Customer Satisfaction**	**X**	**X**
EN 2.04.01	Design and Development Planning	X	
EN 2.04.02	Design Review	X	
EN 2.04.03	Design Verification and Validation	X	X
EN 2.04.04	Product Qualification Report (PQR)	X	X
EN 2.04.05	Engineering Changes	X	X

Procedure title	Procedure title	BRK	HMO
EN 2.04.06	Tooling (Estimation, Design and Fabrication)	X	
EN 2.04.07	Standards for Engineering Documentation	X	X
EN 2.04.09	Product and Documentation Identification	X	X
EN 2.04.10	Risk Management	X	X
EN 2.04.11	Process and Software Validation	X	X
QP 2.05.01	Quality System Documentation	X	X
QP 2.05.02	Good Documentation Practices	X	X
OP 2.06.01	Purchasing	X	
QP 2.06.01	**Supplier Quality Management**	**X**	
QP 2.07.01	Customer Supplied Material	X	X
QP 2.08.01	Product Identification and Traceability	X	X
QP 2.09.01	Process Control	X	X
OP 2.09.01	Equipment Maintenance	X	X
QP 2.10.01	Receiving Inspection	X	X
QP 2.10.02	In-Process Inspection	X	X
QP 2.10.03	Final Inspection	X	X
QP 2.11.01	Control of Monitoring and Measuring Equipment	X	X
QP 2.12.01	Inspection and Test Status	X	X
QP 2.13.01	Control of Non-Conforming Product	X	X
QP 2.13.02	Stock Purge	X	X
QP 2.14.01	Corrective and Preventive Action	X	X
OP 2.15.01	Product Handling and Storage	X	X
QP 2.16.01	Records	X	X
QP2.16.02	Device History Record Requirements	X	X
QP 2.17.01	Internal Auditing	X	X
QP 2.18.01	Employee Training and Competencies	X	X
QP 2.20.01	Measurement, Analysis and Continuous Improvement	X	X
QP 2.85.01	Handling of Customer Complaints	X	X
QP 2.85.02	Recall and Advisory Notice	X	X