

# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 1 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

**TABLE OF CONTENTS**

**MISSION STATEMENT**

**QUALITY POLICY**

**CONTROL OF MANUAL**

**QUALITY SYSTEM CROSS-REFERENCE MATRIX**

**QUALITY SYSTEM ISO 9001:2015**

**CLAUSE 4: CONTEXT OF THE ORGANIZATION**

**CLAUSE 5: LEADERSHIP**

**CLAUSE 6: PLANNING**

**CLAUSE 7: SUPPORT**

**CLAUSE 8: OPERATION**

**CLAUSE 9: PERFORMANCE EVALUATION**

**CLAUSE 10: IMPROVEMENT**

**ADDENDUM A: MEDICAL DEVICE REGULATORY COMPLIANCE**

**ADDENDUM B: INTERNAL CONTROLS-COSO FRAMEWORK**

**(MANAGED BY THE PLANT CONTROLLER)**

**ADDENDUM C: REGULATORY/REGISTRAR/NOTIFIED BODY CONTACT INFORMATION**

**ADDENDUM D: OBLIGATION TO INFORM**

**QUALITY SYSTEM ISO 13485:2016 STARTS ON PAGE 38**

**CLAUSE 4: QUALITY MANAGEMENT SYSTEM**

**CLAUSE 5: MANAGEMENT RESPONSIBILITY**

**CLAUSE 6: RESOURCE MANAGEMENT**

**CLAUSE 7: PRODUCT REALIZATION**

**CLAUSE 8: MEASUREMENT, ANALYSIS AND IMPROVEMENT**

**ADDENDUM A: MEDICAL DEVICE REGULATORY COMPLIANCE**


**ADDENDUM B: INTERNAL CONTROLS-COSO FRAMEWORK**

**(MANAGED BY THE PLANT CONTROLLER)**

**ADDENDUM C: REGULATORY/REGISTRAR/NOTIFIED BODY CONTACT INFORMATION**

**ADDENDUM D: OBLIGATION TO INFORM**



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 2 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>



## ***QUALITY POLICY***

We are committed to understanding and meeting the needs of our customers and relevant interested parties. We strive to deliver products on time, every time, that meet and exceed the expectations of our customers, while ensuring continuous improvement in the quality of the products delivered.


Continual improvement of our quality management system, as well as maintenance of its effectiveness, is assured by systematically:

- Maintaining and communicating a clear strategic direction for the organization
- Understanding our risks and opportunities and addressing them effectively
- Setting quality objectives and monitoring associated metrics
- Communicating to all employees our quality objectives, as well as each employee's role in meeting them
- Enhancing customer satisfaction through the effective application of the system

All employees shall adhere to the spirit and intent of our quality policy, as well as the directives of the quality management system.



Martin Abbott  
Vice President & General Manager  
January 2022

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 3 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CONTROL OF MANUAL**

Control and revision of the Quality Manual are conducted in accordance with the document control procedures described in Clause 7.5.3 - Control of Documents. Quality Manuals that are issued to customers and to others outside the facility are marked as UNCONTROLLED. Changes to the Quality Manual may be initiated by any employee when it is determined that change is necessary to improve the Quality Management System toward achieving quality objectives. Implementation of any suggested changes to the Quality Manual will need the approval of the Site Lead, the Management Representative, and the VP/General Manager. Any significant changes that would cause a noncompliance to the Quality System will require notification to the affected regulatory or registration agency.



**PRACTICES**

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**


**PAGE: 4 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

**QUALITY SYSTEM CROSS-REFERENCE MATRIX**

ISO 13485:2016 Clauses & CP100 Addendums	Reference Documents	ISO 9001:2015 Clauses	Medical Devices FDA 21CFR820	EU MDD 93-42/EEC, as Amended by Directive 2007/47/EC
4.1	CP230	4.4	820.20	Annex II-3.4
4.2	CP202,204,218,230. DC403,415,417,423,424,616	4.3, 7.5, 7.5.1, 7.5.2, 8.5.6	820.20, 820.40, 820.180, 820.186	Annex II-3.2, Annex II-3.4
5.1	CP100	4.1, 5.1, 5.2	820.5, 820.20	
5.2	SA400	5.1		
5.3	CP100	5.2	820.5, 820.20	
5.4	CP100,230	6.1, 6.2, 6.3, 8.5.6	820.5, 820.20	Annex II-3.4
5.5	CP100	5.3, 7.4	820.5, 820.20	
5.6	CP100	9.3	820.5, 820.20	
6.1	CP100	4.2, 7.1, 7.1.1	820.5, 820.20	
6.2	CP100,200	7.1, 7.1.2, 7.1.6, 7.2, 7.3	820.5, 820.20, 820.25	
6.3	MS400,401,402; PD400,401,402; SD400,401	7.1.3	820.70	
6.4	MS400,401,402; PD400,401,402. SD400,401	7.1.4	820.70	
7.1	CP230; QA401,402,404,405,406,413. TD402	6.1, 8.1	820.20, 820.80	Annex II-3.4
7.2	ED400; SA400; SR401	8.2-8.2.4, 8.5.5	820.30	
7.3	ED400; SR401	8.3-8.3.6, 8.5.6	820.30	Annex II-3.4
7.4	PU400,402; QA401,402,404,405,406,413; TD402	8.4-8.4.3	820.50	
7.5	CP228,229,231; CS400,402; MS400,401,402; PD400,401,402; QA401,402,404,405,406,413; SD400,401; TD402,403; WH400,401,402,405,406,411	8.5-8.5.5	820.60, 820.65, 820.70, 820.86	Annex IV-6.4,
7.6	QA411,412	7.1.5	820.72	
8.1	CP219; QA401,402,404,405,406,413; TD402	9.1, 9.1.1	820.80, 820.250	
8.2	CP219; QA401,402,404,405,406,413,417; TD402	8.6, 9.1, 9.9.1, 9.1.2, 9.2	820.80	
8.3	CP223; QA414,415	8.7, 10.1, 10.2	820.90	
8.4	CP219	9.1.3	820.250	
8.5	CP100; QA421	6.1, 10.1, 10.2, 10.3	820.5, 820.20, 820.100	Annex II-3.1
Addendum A	Medical Devices-CP 207, 223	(ISO 13485)8.1, 8.2, 8.4	820.198	
Addendum B	COSO Framework (Finance)-CP 250			
Addendum C	Contact Information			
Addendum D	Obligation to Inform			
	CP251 - CMDR			

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<b>PRACTICES</b>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 5 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

# ISO 9001: 2015

**CLAUSE 4**

**CONTEXT OF THE ORGANIZATION**

**4.1 UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT**

This Manual document our practices to meet the requirements of the Quality Management System of Teledyne Analytical Instruments (hereinafter called “company”, “our”, “organization”, or “facility”), and demonstrates our ability to consistently provide products and services that meet customer and applicable statutory/regulatory requirements. This manual outlines the steps towards the effective application of the Quality Management System, in route to enhancing customer satisfaction.


As discussed elsewhere, our Mission is to enhance our global market leadership position by meeting the unique needs and exceeding the expectations of the customers we serve. At the heart of this mission is the drive to be a profitable enterprise most admired for our people, partnerships, products, performance, perseverance, and ethical business practices.

Towards achieving the stated mission, the organization has considered the influencers and detractors from both external and internal sources that are relevant to meeting our strategic goal. These are addressed at the macro level through the 3-year strategic plan where we consider amongst others our markets of interest, business environment, politico-economic environment, industry segment trends, competitive positioning, and technology trends. The strategic plan is periodically reviewed, adjusted and actions taken as appropriate. At the tactical levels, relevant issues are addressed through more frequent operational planning- annually through the business plans, through periodic management review meetings, periodic all-hands meetings and down to weekly staff meetings.

**4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES**

There are various interested parties that would positively or adversely influence our stated mission, policy, and objectives. The Company periodically monitors the interested parties and actively interacts with critical ones to sustain the quality management system.

- Partial list of Internal Interested Parties and examples of monitoring/review:
  - Corporate Operations - Weekly/Quarterly/Yearly business reports


 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 6 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

- Corporate Accounting - business audits
- Corporate EH&S - audits and compliance reports
- Corporate Legal – contract evaluation, etc.
- Corporate IT support
- Intra and interdepartmental teams – various meetings and internal reports & management review
- Strategic Business Units Teams Within the Reporting Business Unit
- Partial list of External Interested Parties and examples of monitoring/review:
  - Vendors – vendor evaluation reports
  - Customer/Potential customer – meetings with key influences to understand needs and expectations.
  - Compliance bodies – Standards, Codes & Statutes – Regulatory Agencies, Notified Bodies, Registrars, Certifying Agencies, etc.
  - Outside Processing partners – Drawings, Purchase Orders, Receiving Inspection reports, etc.
  - Local, City, County & State Governments – Manufacturing licenses, Permits, etc.
  - Peacekeeping agencies – Local Police & Fire Departments

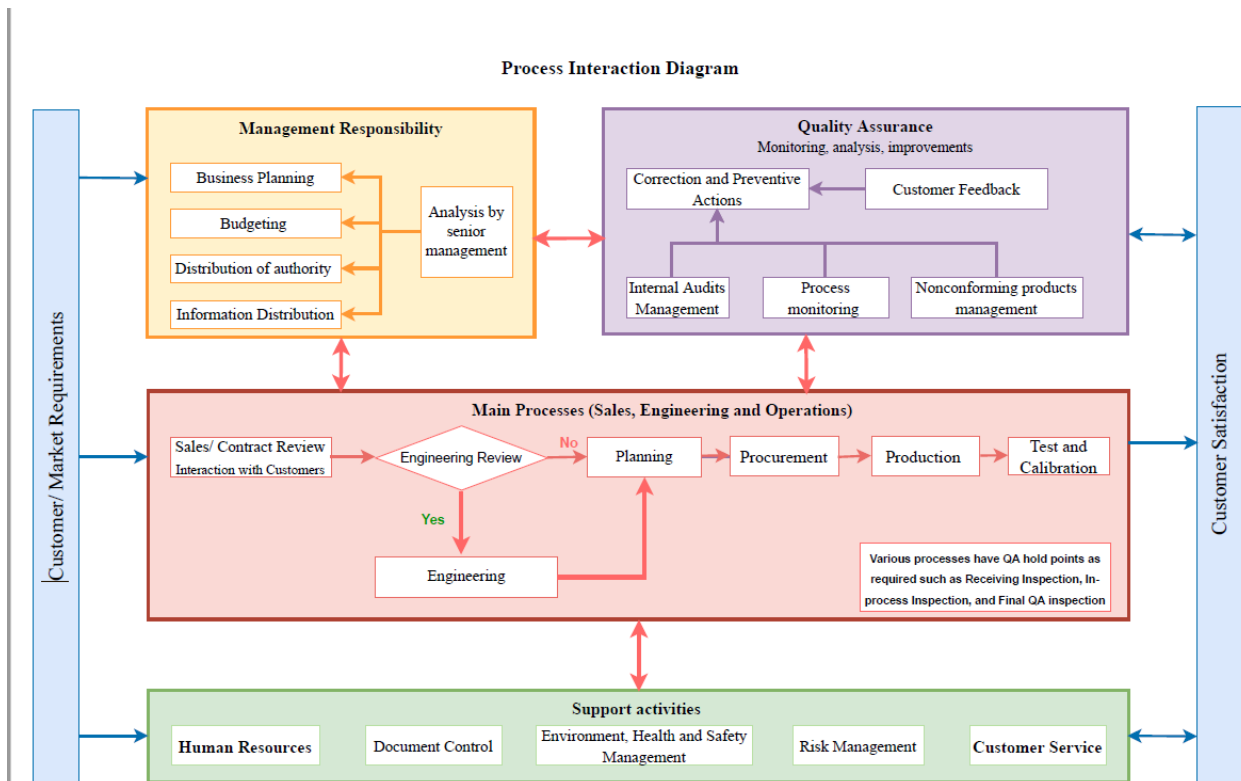
### 4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

This Manual forms the framework of our Quality Management System. This practice defines the quality system implemented at our facility and complies with the requirements of various Standards, Directives, and Regulations such as ISO 9001:2015 (compliance is without exclusion), ISO 13485:2016 (compliance is without exclusion), ISO 80079-34, ATEX Directive 2014/34/EU, Directive 2007/47/EC Including MDR EU 2017/745, Article 120 and 21CFR820.

- The purpose of this Quality Manual is to describe and document the Quality System implemented within our company.
- This manual is the central source of general practices and procedures that authorize and govern the creation of subsidiary quality systems-related documentation and activities.
- This manual provides comprehensive evidence to customers, suppliers, and employees that the company is committed to establishing and maintaining acceptable levels of Quality in its products and services.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS <i>Everywhere you look™</i>	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 7 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>


## 4.4 QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES




This Quality Manual describes the quality system implemented and maintained at our facility that, amongst others, complies with the requirements of various standards mentioned elsewhere in this document.


Key processes determined for incorporation into our Quality Management System and their interactions are outlined below. These requires application of a risk based approach control of the appropriate processes. These are monitored, and where applicable, measured, and analyzed.

- **Management System**
  - Administered by the Executive Management, this process defines the Quality Policy and sets Quality Objectives and is responsible for communicating these to all ranks within the company. This process is also responsible to ensure general availability of resources and information necessary to support the company operations. Management is responsible for business planning, budgeting, distribution of information and authority.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 8 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>
<ul style="list-style-type: none"> <li>○ Executive Management, with assistance from Departmental Management, has the overall responsibility to implement actions necessary to achieve planned results and maintain the effectiveness of the company processes.</li>   <li>▪ Sales/Contract Review <ul style="list-style-type: none"> <li>○ Input to this process is in the form of inquiries, requests for quotations, or purchase orders/contracts from the customers. Each inquiry or contract received is reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. The results from this process will be the inputs to either the Engineering or Operations functions.</li> </ul> </li>   <li>▪ Engineering <ul style="list-style-type: none"> <li>○ This process involves all research and sustaining engineering activities. Sales and Marketing driven inputs to this process result in products engineered to specific customer needs or designed to fulfill discovered market opportunities.</li> </ul> </li>   <li>▪ Operations <ul style="list-style-type: none"> <li>○ This process encompasses the Document Control, Production Control, Purchasing, Warehousing, Manufacturing, Test &amp; Calibration,, and Shipping functions of the company. This complex process has inputs typically coming from either the Sales or Engineering functions into the Production Control function, which then forms the feeder to the remainder of the Operations process. The typical final output from the Operations process is the manufactured Product. The Product will be verified by the Quality process to ensure compliance to the customer/regulatory/notified body requirements prior to forwarding the Product to the Shipping function for shipment.</li>   <li>○ Control of the products/processes outsourced will be administered as outlined in the Purchasing Department procedures.</li> </ul> </li> </ul>		



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 9 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>
<ul style="list-style-type: none"> <li>▪ <b>Quality Assurance</b> <ul style="list-style-type: none"> <li>○ This process is responsible to ensure continued compliance of the company’s Quality System to various standards adopted by the company.</li> <li>○ This process has the responsibility to ensure that the requirements of the customers, regulatory bodies, notified/registrar bodies, and of the company’s internal procedures are in harmony and are reflected in our products, and in the event of any nonconformance, take necessary steps, including Corrective &amp; Preventive actions, to correct such non-conformance.</li> <li>○ This process is responsible to maintain continued compliance with the company’s Quality System through periodic internal audits.</li> <li>○ The input to this process is from customers, operations, and regulatory authorities. While the output of this process is management review, process monitoring, customer satisfaction, and regulatory compliance.</li> </ul> </li>   <li>▪ <b>Customer Service</b> <ul style="list-style-type: none"> <li>○ This process is responsible for all product’s post-sales issues. This process also maintains metrics to measure the company’s performance related to post-sales customer feedback and vigilance in route to maintaining continual customer satisfaction.</li> </ul> </li>   <li>▪ <b>Human Resources</b> <ul style="list-style-type: none"> <li>○ This process is responsible to ensure that the personnel performing work affecting product quality and related supporting functions are competent, based on appropriate education, training, skills, and experience.</li> </ul> </li> </ul>		

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 10 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 5**

**LEADERSHIP**

**5.1.1 LEADERSHIP AND COMMITMENT**

In our quest to continually improve the quality of our products and to achieve the goals of Customer Satisfaction and applicable statutory and regulatory compliance, the Executive Management of the company is committed to the summary implementation of the Quality Management System in accordance with the framework presented in this Quality Manual.


This objective is achieved through:

- Clear and periodic communications with the management team and the employees regarding the importance of meeting the requirements of the customers, standards, regulatory agencies, registrar, and notified bodies and of our Quality Management System. Management at all levels of the organization should consider the impact of its quality process regarding risk assessment, mitigation, and evaluation. A partial list of forums used for such communications are:
  - Management Review Meetings
  - Staff Meetings
  - Company All-hands Meetings
- Establishment of the Quality Policy and execution of the Quality Objectives.
- Ensuring that requisite resources - qualified personnel, equipment, and facility - are in place.

**5.1.2 CUSTOMER FOCUS**

Each contract or order that is received is reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. Our capabilities are assessed in relation to the customer requirements to determine our ability to accept the order. The review will also include any statutory and regulatory requirements related to the product or order.

If the customer’s requirements are different from our capabilities, then those differences are communicated to the customer and any issues are resolved prior to our accepting the order.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 11 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

The Customer Service function will address the post-sales product-related issues along with maintaining relevant metrics to measure/monitor the company’s performance related to post-sales customer feedback and vigilance en route to maintaining continual customer satisfaction.

## 5.2 POLICY

The Top Management of the company is committed to continual improvement of the quality of our products, satisfaction of our customers, and compliance with applicable statutory/regulatory requirements. Management is also committed to complying with the requirements and maintaining the effectiveness of our Quality Management System. This Policy is communicated to all ranks within the organization and is periodically reviewed for its continued suitability.

## 5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES, AND AUTHORITIES

This practice defines the company’s responsibility, authority, and interrelationship with all personnel.


The organization is structured functionally with all the department heads reporting directly to the VP/General Manager. The Human Resources and the Finance functions have an indirect reporting responsibility to General Manager.

Independent of his/her position, any individual in the company has the authority to stop the product that he/she feels does not meet quality requirements.

All employees are responsible for fulfilling the quality system requirements for their respective areas. All employees have the authority to identify problems and to initiate, recommend or provide solutions through their department supervisor, or manager.

Quality Assurance Department principally has the responsibility to identify and record non-conformances, and the authority to initiate action to prevent noncompliance issues to the product, process, and quality system.

The Material Review Board (MRB) (consisting of representatives from the Production, Engineering, and Quality Assurance Departments) is responsible for recommending, providing, and implementing solutions to correct and prevent non-conformances.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 12 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**MANAGEMENT REPRESENTATIVE**

The Company’s Management Representative reports to the top management and is assigned with the responsibility and the requisite authority to ensure that the processes required to administer the quality management system are established and implemented.

Management Representative is also responsible for and has the appropriate authority to ensure compliance with the requirements of various Standards/Regulatory/Registrar/Notified bodies.

Management Representative will ensure the promotion of regulatory and customer requirements and is responsible for reporting to the company’s management on the performance of the Quality System and any recommended changes and improvements to the system.

Management Representative: As appointed by the Head of the Organization, VP of Operations/ QA. See company organizational chart for current appointment.



# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 13 OF 76**


**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

## ORGANIZATIONAL CHART

Refer to the link below for the Current Organizational Chart

<L:\Dept\QA\QA\Organization Chart 2022\TAMS Org Chart 12.2022, MR, M. Khan.pdf>

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 14 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 6**

**PLANNING**


**6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES**

In keeping with the quality management system, the company has adopted the following plan and developed processes and procedures for risk management needed to manufacture the product.

- Preparation of Quality Plans (Route Sheets).
- Identification and acquisition of controls, processes, equipment, fixtures, resources, and training that may be required.
- Ensuring the compatibility of the design, processes, inspection, and testing procedures and applicable documents.
- Ensuring that inspection and testing documents are updated as needed.
- Identification of verification, validation, monitoring, and measurement requirements that meet the known state of the art to allow for the development of adequate techniques.
- Identification of required and/or necessary inspection and test operations in the product flow to achieve product acceptance.
- Inspection and test criteria shall be clarified, particularly those criteria that may be subjective.
- Identification and preparation of quality records (For medical devices this includes the device master file).
  - Files shall be maintained defining the type and/or model of the Medical Device, corresponding product specifications, manufacturing process methods, installation, and service, as applicable.
- Any other documentation required by Domestic or International regulations.

Documented procedures have been implemented for inspection and testing activities in order to verify that specified requirements are satisfied. Records of the required inspection and testing are defined in the procedures.

The internal audit process verifies the effectiveness of the product realization plan.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 15 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

## 6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM


We assess the success of our Quality Objectives through frequently collected measurable data that are discussed during our periodic Management Review sessions. The specific and measurable Quality Objectives are:

- First Pass Yield
  - Instruments
  - Spares
- Sensor Production Yield
- Price of Nonconformance
  - Cost of Scrap
  - Cost of Rework
  - Cost of Warranty
- On-Time Delivery
  - To our customers
  - From our Suppliers
- Linear Shipment

## 6.3 PLANNING OF CHANGES

Through the provisions and processes mentioned under Clause 4.4 of this document, augmented by the company/departamental procedures and work Instructions, the top management of the company ensures that the quality management system complies with the meets the quality policy and strives to achieve the goals set for quality objectives.

Configuration Control Board authorization will be required before implementing any changes to the quality system. Changes to this quality manual will require approval by the top management.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<b>PRACTICES</b>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 16 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 7**

**SUPPORT**

**7.1 RESOURCES**

Company’s Management shall identify resource requirements and provide adequate resources to implement the Quality Management System and maintain its effectiveness, enhance customer satisfaction, and meet regulatory and customer requirements. The term “resources” is used in this paragraph to include Human, Facility, and Environmental resources.

**7.1.1 GENERAL**

As noted above, the company’s Management shall identify the human resource requirements and provide adequate resources to enhance customer satisfaction and meet regulatory and customer requirements. This includes the assignment of trained personnel for management, the performance of, work, and verification activities including internal quality audits.

**7.1.2 PEOPLE**

This practice defines the provisions made within the company to ensure that all personnel is adequately trained for the tasks that they are required to undertake.

Documented procedures have been implemented to identify training needs and the training of all personnel performing activities affecting product quality and conformity. The objective is to ensure the employees are aware of the importance of, and how they contribute to, their activities.

Personnel performing specific assigned tasks are qualified based on education, experience, and/or training.

Records of training are maintained.



# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 17 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

## 7.1.3 INFRASTRUCTURE

The top management has allocated and maintained the necessary infrastructure in keeping with the strategic growth plans for the company. The infrastructure development includes building management, workspace development, conformity to product requirements, preventing product mix-up, office/process equipment, communications equipment, information systems, and utility maintenance. The adequacy of the company's infrastructure will be reviewed, and changes are made as needed to meet the growth initiatives.

## 7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

### WORK ENVIRONMENT

The company has identified and planned the production and servicing processes that directly affect product quality and shall ensure that these processes are carried out under a controlled environment which includes:


- Documented procedures defining the method of production.
- Use of suitable production equipment and a suitable working environment to achieve product conformity.
- Criteria for workmanship as defined in the written standards, representative samples, photos, and/or illustrations.
- Manufacturing equipment maintenance plans to ensure continuing process capability.
- Procedures for Electrostatic Discharge Protection and Personal Protection Equipment to help eliminate any adverse effects due to interaction amongst the personnel, product, and the work environment.

### CONTAMINATION CONTROL

The company has identified and planned the processes for the control of contamination that directly affect product quality and personnel. Medical devices supplied by the company are not sterile devices or designed to be sterilized in use.

## 7.1.5 MONITORING AND MEASURING RESOURCES

Documented procedures have been implemented to control, calibrate, and maintain inspection, measuring, and test equipment used to demonstrate conformance to the product to specified requirements.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 18 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

The inspection, measuring, and test equipment will be used in a way that is consistent with the measurements it is required to make.

Inspection, measuring, and test equipment are identified, calibrated, and adjusted at prescribed intervals against certified equipment having known relationships to national or international standards. Where no such standards exist, the basis for calibration shall be documented.

Steps are taken to ensure that the environmental conditions are suitable when calibration of inspection, measurement, and test equipment is performed.

Inspection, measuring, and test equipment are tracked by equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and action to be taken when the results are unsatisfactory.

Test software and hardware are tested on a regular basis to ensure continuing suitability. Records or such checks are maintained.

Where required by customers, technical data on inspection, measuring, and test equipment shall be available.


Inspection, measuring, and test equipment have their calibration status clearly identified and verifiable by the operator/inspector.

When inspection, measuring, and test equipment are found to be out of calibration, an evaluation shall be made and documented to address the product tested on the suspected inspection equipment.

Records for calibration of inspection, measuring, and test equipment are maintained. Inspection, measuring, and test equipment are stored in such a way that fitness for use is maintained and safeguarded against adjustments that would invalidate calibration.

**7.1.6 ORGANIZATIONAL KNOWLEDGE**

The top management will periodically discuss with the company’s management team and the employees the importance of meeting the requirements of the customers, standards, regulatory agencies, registrar, and notified bodies of our Quality Management System. We assess the success of our Quality Objectives through frequently collected measurable data that are discussed during our periodic Management Review sessions. Clear and periodic communications with the management team and the employees regarding the importance of meeting the requirements of the customers, standards, regulatory agencies,

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 19 OF 76</b> <b>REV: 25    REV DATE: 2023-02-14</b> <b>ECO #: 23-0006</b>

registrar, and notified bodies and of our Quality Management System. A partial list of forums used for such communications are:

- Management Review Meetings
- Staff Meetings
- Company All-hands Meetings
- Post-sales customer feedback and vigilance

## 7.2 COMPETENCE

As noted under Clause 7.1, the company’s Management shall identify the human resource requirements and provide adequate resources to enhance customer satisfaction and meet regulatory and customer requirements. This includes the assignment of trained personnel for management, the performance of work, and verification activities including internal quality audits.

## 7.3 AWARENESS

This practice defines the provisions made within the company to ensure that all personnel is adequately trained for the tasks that they are required to undertake.

Documented procedures have been implemented to identify training needs and the training of all personnel performing activities affecting product quality and conformity. The objective is to ensure the employees are aware of the importance of, and how they contribute to, their activities.

Personnel performing specific assigned tasks are qualified based on education, experience, and/or training.


Records of training are maintained.

## 7.4 COMMUNICATION

The top management will periodically discuss with the company’s management team and the employees the importance of meeting the requirements of the customers, standards, regulatory agencies, registrar, and notified bodies of our Quality Management System.

## 7.5 DOCUMENTED INFORMATION

### 7.5.1 GENERAL

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 20 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

This section incorporates by reference our Mission, our Quality Policy, and our Quality Objective as illustrated elsewhere in this Quality Manual document.

The Quality System is structured into three levels of documentation:

1. Level One is documented in the form of a Quality Manual, which contains the Practices of the company.
2. Level Two documents are the departmental procedures that are referenced in the Quality Manual, which implement the quality system and quality policy.
3. Level Three documents are specific departmental work instructions utilized in most cases to carry out a specific task.

Records in support of the Quality System are maintained as outlined in section 7.5.3.

### 7.5.2 CREATING AND UPDATING

Documents applicable to the Quality System defined in this Quality Manual are subject to review for adequacy, update, and approval by authorized personnel prior to issue.


This entire document forms the framework of our Quality Management System and is hereby incorporated as our Quality Manual. As described elsewhere, this Manual establishes the Scope of our Quality Management System and outlines various procedures as Reference Documents in support of our Quality Management System.


#### MEDICAL DEVICE FILE

For each Medical Device type or medical device family, the company shall establish and maintain a device master record (technical file) containing all technical information about the device. Where applicable, the technical file will also include copies of manufacturing processes and installation/maintenance guidelines.

### 7.5.3 CONTROL OF DOCUMENTED INFORMATION

- Documentation will be controlled to ensure the availability of current, pertinent and relevant information to all functioning organizations at the points of use.
- Documentation changes are reviewed by the Configuration Control Board (CCB), if necessary. CCB representatives have access to pertinent information needed to approve/reject changes.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 21 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>
<ul style="list-style-type: none"> <li>▪ A Master List of all documents applicable to this Quality System has been established and is maintained and readily available to preclude the use of invalid and/or obsolete documents.</li> <li>▪ Documents of external origin necessary to comply with the Quality Management System, such as Standards documents, are under document control.</li> <li>▪ Obsolete documents are removed to prevent inadvertent use. Documents that are retained for legal or historic purposes are labeled “obsolete” to ensure they are not mistakenly used. For critical equipment such as nuclear containment monitors and medical devices, obsolete documents will be maintained for at least the lifetime of the equipment.</li> </ul> <p style="text-align: center;"><b>CONTROL OF RECORDS</b></p> <ul style="list-style-type: none"> <li>▪ Documented procedures have been implemented for the identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.</li> <li>▪ Records demonstrating conformance to specified requirements and the effective implementation of this quality management system are maintained.</li> <li>▪ Records will be legible, retrievable, stored, and maintained in a safe, secure environment to prevent damage, deterioration, and loss.</li> <li>▪ Quality Records retention times are incorporated into the Quality Manual through reference to the Control of Quality Records Procedure CP204.</li> </ul>		

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 22 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 8**

**OPERATION**


**8.1 OPERATIONAL PLANNING AND CONTROL**

In keeping with the quality management system, the company has adopted the following plan and developed processes and procedures for risk management needed to manufacture the product.

- Preparation of Quality Plans (Route Sheets).
- Identification and acquisition of controls, processes, equipment, fixtures, resources, and training that may be required.
- Ensuring the compatibility of the design, processes, inspection, and testing procedures and applicable documents.
- Ensuring that inspection and testing documents are updated as needed.
- Identification of verification, validation, monitoring, and measurement requirements that meet the known state of the art to allow for the development of adequate techniques.
- Identification of required and/or necessary inspection and test operations in the product flow to achieve product acceptance.
- Inspection and test criteria shall be clarified, particularly those criteria that may be subjective.
- Identification and preparation of quality records (For medical devices this includes the device master file).
  - Files shall be maintained defining the type and/or model of the Medical Device, corresponding product specifications, manufacturing process methods, installation, and service, as applicable.
- Any other documentation required by Domestic or International regulations.

Documented procedures have been implemented for inspection and testing activities in order to verify that specified requirements are satisfied. Records of the required inspection and testing are defined in the procedures.

The internal audit process verifies the effectiveness of the product realization plan.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 23 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**8.2 REQUIREMENTS FOR PRODUCT AND SERVICES**

**8.2.1 CUSTOMER COMMUNICATION**

**8.2.2 DETERMINING THE REQUIREMENTS FOR PRODUCTS AND SERVICES**

**8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES**

**8.2.4 CHANGES TO REQUIREMENTS FOR PRODUCTS AND SERVICES**

The Customer Service and Quality Assurance functions will perform the post-sales product-related customer communications along with maintaining relevant metrics to measure/monitor the company’s performance related to post-sales customer feedback and vigilance, including handling customer complaints and issuance of any advisory notices.

Requests for proposals or contracts or orders are reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. Our capabilities are assessed in relation to the customer requirements to determine our ability to accept the order. The review will also include any statutory and regulatory requirements related to the product or order and any additional requirements determined by TAI.

If the customer’s requirements are different from our capabilities, then those differences are communicated to the customer and any issues are resolved prior to our accepting the order.

Amendments to contracts are identified and revised requirements are distributed to appropriate functions. When applicable, contract amendments will be evaluated to ensure compatibility with registrar/notified body certifications.


The proposal, product brochure, or order acknowledgment serves as the document to confirm the requirement of the customer.

The records of the review will be maintained.

**8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES**

**8.3.1 GENERAL**

Documented procedures have been implemented for design and development.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 24 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

### 8.3.2 DESIGN AND DEVELOPMENT PLANNING

Plans are prepared for each design and development activity. The plans describe or reference these activities, including verification and/or validation actions and reviews deemed appropriate for each design and development stage. The plan also assigns responsibilities to qualified employees for the completion of the activities, including the design transfer activities prior to production. The plans are updated as designs evolve. Resource and Technical Interfaces between different departments of the company that provide input into the design process are documented, transmitted, and reviewed.

### 8.3.3 DESIGN AND DEVELOPMENT INPUTS

All design requirements such as functional/performance, statutory/regulatory, and safety requirements and statutes related to the product design and intended use are identified, documented, reviewed, and approved. Incomplete, ambiguous, and conflicting requirements are resolved with personnel imposing these requirements. When applicable, the design input process will take into consideration the results of any contract review activities, requirements of any statutory/regulatory bodies, the result of risk management study, and usability.


### 8.3.4 DESIGN AND DEVELOPMENT CONTROLS

At appropriate stages of design and before product release, formal design reviews are conducted in accordance with the Design and Development Planning. Representatives of all functions involved in that stage of the design, competent independent observers, and others as deemed necessary will participate in these reviews which will include the identification of the design under review, representatives and date of the review. Review records are maintained.

Verification of design is conducted at appropriate stages to ensure that the design stage output meets the design stage input requirements. These verification measures are recorded.

Design validation is performed to ensure that the product conforms to defined user needs and/or requirements. Validation shall be completed prior to production activities. Where necessary, such validation shall entail off-site studies such as EMI/RFI studies, clinical trials, and the like. The validation records are maintained.



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 25 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

### 8.3.5 DESIGN AND DEVELOPMENT OUTPUTS

All design outputs are verified/validated, documented, and maintained against the design input requirements. Design output requirements shall meet or exceed the input requirements, contain, or reference acceptance criteria and identify those characteristics that are crucial to product safety and the safe and proper functioning of the product. Design output documents are reviewed for completeness prior to release to purchasing, production, and service functions. Records of the activity are maintained.

Design changes and modifications are reviewed and approved by authorized personnel prior to release to operations.

### 8.3.6 DESIGN AND DEVELOPMENT CHANGES

Before implementation, design changes and modifications are identified, documented, reviewed, and approved by authorized personnel. Changes effect should be made to products in process and on the output of risk management and product realization processes and the significance of a design and development change.

Design and development changes for each medical device are recorded and maintained.

## 8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS, AND SERVICES


### 8.4.1 GENERAL

The suppliers are selected based on their ability to meet the company's Quality System requirements.

Measures of evaluation, selection, and re-evaluation of sub-contractors are documented and shall include one or more of the following:

- Type of product
- Evaluation of the sub-contractor's previous inspection history.
- Sub-contractor's technical and quality capability as determined by an audit of the sub-contractors and quality system.
- Sub-contractor's achievement of an internationally approved quality system.
- The impact of the supplied product in meeting the quality of the final product.
- The impact of the supplied product with the risk associated with a medical device.

Records of approved suppliers are maintained.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 26 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

### 8.4.2 TYPE AND EXTENT OF CONTROL

The right to verify materials at source, when necessary, will be specified in the purchase document.

Where required by contract, the right of access to company and sub-contractor facilities/records for product verification will be made available.

Verification of the product by the customer shall not be used by the company as evidence of effective control of quality by the sub-contractor.

Verification of the product by the customer does not relieve the company of the responsibility to provide an acceptable product, nor does it preclude subsequent rejection by the customer.


No purchased product shall be used until it has been inspected, or otherwise verified as conforming to specified requirements or considered dock-to-stock based on vendors' history. Activity records are maintained.

### 8.4.3 INFORMATION FOR EXTERNAL PROVIDERS

Purchase Orders and documents containing requirements for products being ordered shall include, as applicable:

- Type, class, grade, or other precise identification.
- Positive identification, including titles, numbers, revision levels, special requirements, and instructions, including approval or qualification of product, procedures, traceability (critical components and materials), process equipment, and personnel.
- Applicable Quality System standards.

Procurement documents are reviewed and approved for adequacy of the specified requirements prior to release. Copies of the purchase orders are maintained.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 27 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**8.5    PRODUCTION AND SERVICE PROVISION**

**8.5.1    CONTROL OF PRODUCTION AND SERVICE PROVISION**

These practices define the way in which the manufacturing and servicing processes will be controlled, and where required,


The company has identified and planned the production and servicing processes that directly affect product release, product quality, delivery, and post-sales activities, and shall ensure that these processes are carried out under controlled infrastructure which includes:

- Documented procedures and work instructions defining the method of production.
- Use of suitable production, monitoring, and measuring equipment and a suitable working environment to achieve product conformity.
- Monitoring and control of the suitable process and production parameters.
- The approval of processes and equipment, as appropriate.
- Criteria for workmanship as defined in written standards, representative samples, photos, and/or illustrations.
- Manufacturing equipment with maintenance plans to ensure continuing process capability.
- Protection of products after final inspection and test. Where required, this protection will be extended to the delivery to the destination.
- Servicing process control, utilizing post-production activities or customer feedback. Records of any factory service performed shall be maintained.
- Validation of any software.

Any process that cannot be verified by subsequent inspection and testing will be carried out by qualified operators and/or the process parameters will be controlled and monitored continuously and revalidated, as necessary, to ensure specified requirements are met. The requirement for qualification of any operation or operator will be documented and records maintained.

Medical devices supplied by the company are not sterile devices nor designed to be sterilized in use. Their cleanliness is not significant in use. Hence, the referenced clause of the standard is not applicable to the company.

Devices supplied are oxygen analyzers, monitors, and sensors, requiring no factory-assisted installation.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 28 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**8.5.2 IDENTIFICATION AND TRACEABILITY**

This practice defines how product identification and traceability will be maintained.

The product shall be identified through all stages of production to delivery. Identification will be provided through physical identification (marking or tags) wherever practical. When physical identification is impractical, appropriate means of identification will be used.

When traceability is a specified requirement, the company maintains procedures that define the method used for the identification of the individual product or lot to specific documentation such as purchase order, work order, and/or sales order number. This identification will be recorded.

The inspection and test status of the product are identified by suitable means (e.g., monitoring, measurement), which indicate the conformance or nonconformance of the product regarding inspections and tests performed. Records of inspection and test are maintained.

**8.5.3 PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS**

The company ensures that any customer-supplied product or information for incorporation into the final product is identified, verified, stored, and maintained. If such a property is inadvertently lost, damaged, or otherwise found unsuitable for use, this shall be reported to the customer and records shall be maintained.


**8.5.4 PRESERVATION**

Documented procedures have been implemented for the identification, handling, storage, packing, preservation, and delivery of the product.

The product is handled in such a way as not to damage the product.

Designated storage areas are used to prevent damage to the product pending use or delivery.

The product will be packaged and marked to ensure product quality and identification requirements are maintained.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 29 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

The product is preserved through appropriate methods to ensure ongoing fitness for use. Product subject to deterioration with age or with a specified shelf life will be controlled.

**8.5.5 POST-DELIVERY ACTIVITIES**

The Customer Service and Quality Assurance functions will perform the post-sales product-related customer communications along with maintaining relevant metrics to measure/monitor the company’s performance related to post-sales customer feedback and vigilance, including handling customer complaints and issuance of any advisory notices.

**8.5.6 CONTROL OF CHANGES**

Before implementation, design changes and modifications are identified, documented, reviewed, and approved by authorized personnel. Changes effect should be made to products in process and on the output of risk management and product realization processes and the significance of a design and development change.

Configuration Control Board authorization will be required before implementing any changes to the quality system. Changes to this quality manual will require approval by the top management.


**8.6 RELEASE OF PRODUCTS AND SERVICES**

No product shall be used until it has been inspected, or otherwise verified as conforming to specified requirements. Verification of the specified requirements is performed to the Quality Plan and/or documented procedures.

In-process inspection and test steps are defined in the Quality Plan and/or procedures.

All Final Inspection and Testing will be completed in accordance with the Quality Plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

In addition to the inspection of finished product characteristics, checks will be made to establish that all previous inspections and tests have been carried out with satisfactory results.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 30 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

The product will not be released until all required inspections and tests determine whether the product has conformed to requirements or deviations have been approved by the customer or relevant authority.

Records of inspection and test are maintained. These records clearly show whether the product has passed or failed the inspections and/or tests defined in documented criteria. Products that fail any inspection and/or test will be handled in accordance with the procedure for the control of nonconforming products.

Records are also maintained of the individuals having authority and responsibility to release products.

## **8.7 CONTROL OF NONCONFORMING OUTPUTS**


Documented procedures have been implemented to ensure that a product that does not conform to specified requirements is prevented from unintended use, installation, or delivery.

The system for the control of the nonconforming product, detected before and after delivery, provides for the identification, documentation, evaluation, segregation, disposition of nonconforming products, and notification to the functions concerned.

The responsibility for review and authority for the disposition of nonconforming products is defined in documented procedures. The review and disposition of Non-conforming products such as use as is, reject, repair, or rework is performed in accordance with documented procedures. Where required, any statutory/regulatory guidance shall be considered.

When required by contract, a product that does not conform to the customer's specification will only be used or supplied with the customer's prior knowledge and written consent. A description of the actual condition that has been accepted, with possible concessions or deviations, shall be recorded.

Any product that is repaired or reworked shall be re-inspected according to a Quality Plan and/or documented procedure.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 31 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 9**

**PERFORMANCE EVALUATION**

**9.1.1 MONITORING, MEASUREMENT, ANALYSIS, AND EVALUATION**

As discussed elsewhere, through the provisions and processes mentioned under Clause 4.4 of this document and augmented by the company/departmental procedures and work Instructions, the company ensures that proper monitoring, measurement, analysis, and improvement processes are established to ensure conformity to and maintain/improve the effectiveness of the quality management system.

Documented procedures have been implemented for inspection and testing activities in order to verify that specified requirements for the product are satisfied. Records of the required inspection and testing are defined in the procedures.


Statistical techniques are employed where applicable for establishing, controlling, and verifying process capability and product characteristics. The key performance indicator (KPI) data are collected and analyzed for trends and identification of improvement opportunities. The data will be distributed for management and factory personnel knowledge and awareness.

**9.1.2 CUSTOMER SATISFACTION**

As part of the KPI data, the company will gather post-sales product performance and customer feedback data for analysis and possible implementation of improvements to ensure that the company has met the customer requirements and has achieved continued customer satisfaction. The aspects of customer perception on our performance and customer satisfaction are crucial to the survival of the company. These performance indicators are verified and validated during the pre-sales and post-sales customer visits undertaken by various personnel of the company.

**9.1.3 ANALYSIS AND EVALUATION**

Statistical techniques are applied to gather and analyze the KPI data to demonstrate the effectiveness of the quality management system and evaluate steps toward the continual improvement of the system and help gauge customer satisfaction. The results of the analysis will be discussed at the management review meetings.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 32 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**9.2    INTERNAL AUDIT**

This practice defines the conduct of internal quality audits. The intent is to monitor and measure quality system processes and demonstrate ability of the system to achieve planned results.

Documented procedures have been implemented for the performance of regularly scheduled internal quality audits to verify that activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Audits are planned and scheduled based on the status and importance of the activity being audited. Individuals who do not have direct responsibility for the activities being audited perform these audits.

Audit results will be recorded and reported to personnel responsible for the activity being audited. The management personnel responsible for the area will take timely corrective action on deficiencies noted during the audit.

Should a nonconformity discovered during the internal audit be significant as to affect the product quality or safety if not immediately corrected, the management of the area being audited shall ensure that immediate and necessary corrections are implemented, and then determine the cause for such nonconformity and take corrective actions to prevent occurrence.

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

Results of internal audits shall comprise part of the management review.


**9.3    MANAGEMENT REVIEW**

**9.3.1    GENERAL**

Top Management will review the Quality System, Policy & Objectives with the company’s management team on an annual basis, as a minimum and not exceed 14 months, to ensure its continued adequacy, suitability, and effectiveness, and to discuss opportunities for improving the quality system.

The certified product liaison under the ATEX directive, i.e., an authorized person, must attend this review.



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 33 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

### 9.3.2 MANAGEMENT REVIEW INPUTS

The review shall address the following as a minimum:

- Action items from the previous management review meetings.
- The audit program (internal/external) – Results of previous audits, and any quality system improvement opportunities resulting from the audits.
- Status of Corrective & Preventive Actions (internal/external)
- Status of the third-party certified products.
- Product conformance profiles and cost of quality discussions.
- Internal (manufacturing) and external (supplier) operational performance – Opportunities and challenges.
- Internal and external (e.g., customer) feedback on product and market performance trends, and recommendations to process improvements.
- The quality system effectiveness with respect to the adopted standard(s).
- Any recommendations for improving the Quality Management System.
- Any new or revised statutory or regulatory requirements.

### 9.3.3 MANAGEMENT REVIEW OUTPUTS

The Management Review is to facilitate the necessary actions and allocate the resources to improve the quality system, processes, and products to comply with customer and statutory/regulatory body requirements. Additionally, the Management Review shall include an evaluation of the adequacy, continuing suitability, and effectiveness of the Quality Management System.


## CLAUSE 10

### IMPROVEMENT

#### 10.1 GENERAL

Documented procedures have been implemented to ensure that a product that does not conform to specified requirements is prevented from unintended use, installation, or delivery.

The system for the control of the nonconforming products, detected before and after delivery, provides for the identification, documentation, evaluation, segregation, disposition of nonconforming products, and notification to the functions concerned.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 34 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

The responsibility for review and authority for the disposition of nonconforming products is defined in documented procedures. The review and disposition of non-conforming products such as use as is, reject, repair, or rework is performed in accordance with documented procedures. Where required, any statutory/regulatory guidance shall be considered.

When required by contract, a product that does not conform to the customer’s specification will only be used or supplied with the customer’s prior knowledge and written consent. A description of the actual condition that has been accepted, with possible concessions or deviations, shall be recorded.

Any product that is repaired or reworked shall be re-inspected according to a Quality Plan and/or documented procedure.

**10.2 NONCONFORMITY AND CORRECTIVE ACTION**

Documented procedures are in place for implementing corrective and preventive action.

The company ensures that conditions adverse to quality such as customer complaints, returns, product nonconformities, and supplier issues, including the degree of magnitude and risk of the nonconformity, are identified and corrected.


When processes are changed as the result of corrective actions, these changes shall be institutionalized, and appropriate procedures updated.

The company ensures customer complaints and reports of nonconformities are handled in a timely, effective manner.

The corrective action will include an investigation of the cause of the nonconformities relating to the product, process, and quality system, and recording the results of the investigation.

The investigation includes the corrective action necessary to prevent a recurrence.

Controls include follow-ups to ensure that the corrective actions are completed, effective, and do not have an adverse effect.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 35 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**10.3 CONTINUAL IMPROVEMENT**

As mentioned elsewhere, through the provisions and processes mentioned under Clause 4.4 of this document, augmented by the company/departmental procedures and work

Instructions, the company ensures that the quality management system meets the quality objective and policy guidance.


In the quest for continually improving the quality of our products and achieving the goal of Customer Satisfaction, the company is committed to the summary implementation of the Quality Management System, including using the avenues of audit results, analysis of data, corrective & preventive actions, and continual customer communication.

The effectiveness of the quality management system will be discussed during the management review meetings.

The organization has established “Medical Product Complaint Handling” and “Product Recall” procedures that act as vehicles for the issuance of customer advisory notices when required.

Customer Complaint Reports generated per the Complaint Handling procedure shall be maintained. When the investigation reveals factors outside of the company that may have contributed to the complaint, such information will be shared with the customer and other relevant organizations.

The Customer Complaint Report (CCR) discusses the disposition of customer complaints and identifies the need for any failure analysis that may lead to corrective/preventive actions. The CCR also identifies the need for any reporting to the Regulatory authorities based on the Medical Product Complaint Handling procedure.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<b>PRACTICES</b>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 36 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**ADDENDUM A**

**MEDICAL DEVICE REGULATORY COMPLIANCE**

**A.    PURPOSE**

This practice defines the company’s methods of complying with the United States Food and Drug Administration (Code of Federal Regulations 21CFR Part 820), European Medical Devices Directive, Canadian Medical Device Regulation, and other applicable statutory and regulatory requirements.

**B.    PRACTICE**

Documented procedures have been implemented to review, evaluate, and file all complaints; to determine if an investigation is necessary; to record the reason if no investigation is made; assign responsibility for deciding when not to investigate; and designate the personnel to perform these activities.

**ADDENDUM B**

**SARBANES-OXLEY 404 - INTERNAL CONTROLS**  
**COSO FRAMEWORK**

This document is under the control of the Plant Controller or designee and is not a part of the company’s Quality Management System, hence, not auditable under ISO 9001:2xxx, ISO 13485:2xxx, or other Company-adopted quality standards.

This document will form the guiding document for our internal financial controls and will be the framework for any Corporate Internal and External audits.



# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 37 OF 76**

**REV: 25 REV DATE: 2023-02-14**


**ECO #: 23-0006**

## ADDENDUM C

### CONTACT INFORMATION

This addendum lists various regulatory, registrar, and notified bodies that are relevant to our business.

Standards, Directives, Regulations	Regulatory/Notified Body/Registrar Contact Information
ISO 9001:2xxx	<p><u>Registrar:</u> Intertek Testing Services 70 Codman Hill Road, Boxborough, MA 01719 T: 978-929-2100; F: 978-635-8595 <a href="mailto:Intertek-sc@intertek.com">Intertek-sc@intertek.com</a></p>
ISO 13485:2xxx and Canadian Medical Device Regulations	<p><u>Registrar:</u> BSI Management Systems, Inc., 12110 Sunset Hills, Ste. 200, Reston, VA 20190 T: 703-437-9000; F: 703-437-9001 <a href="mailto:Inquiry.msamericas@bsigroup.com">Inquiry.msamericas@bsigroup.com</a></p>
European Medical Devices Directive	<p><u>Notified Body:</u> BSI Product Services Kitemark House, Maryland Avenue Hemel Hempstead, HP2 4SQ, UK T: 011-44-1442 278 625; F: 011-44-1442 278 575 <a href="mailto:Product.Services@BSIGroup.com">Product.Services@BSIGroup.com</a></p> <p><u>Competent Authorities:</u> For a current list, refer to <a href="http://ec.europa.eu/enterprise/medical_devices/ca/list_ca.htm">http://ec.europa.eu/enterprise/medical_devices/ca/list_ca.htm</a></p> <p><u>Master Distributor:</u> Viamed Limited 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT, UK T: 011-44-1535 634542; F: 011-44-1535 635582 <a href="mailto:enquiries@viamed.co.uk">enquiries@viamed.co.uk</a></p>
US FDA QSR (21CFR820) 510(k) inquiries	<p>Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation (HFZ-401) 9200 Corporate Boulevard Rockville, MD 20850</p>

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 38 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**ADDENDUM D**

**OBLIGATION TO INFORM (THIS SECTION WILL BE UPDATED AS NEEDED)**

Send/Report What?	To Whom?	By Whom?	By When?
ISO 9001:2xxx Certificate (Number 96-653x)	Customers and others, as needed	Sales and others, as requested (Either send a copy or refer to our web pages)	As required
ISO 13485:2xxx Certificate (Number FM 75659)	Customers and others, as needed	Sales and others, as requested (Either send a copy or refer to our web pages)	As required
Device Manufacturing License Renewal Form (License # 60335)	State of California, Dept of Public Health Food & Drug Branch	Quality Assurance	Before July 1 of the year the license expires
Medical Device – Adverse Event, Significant Change to Product, Process or Quality System	Regulatory Bodies (FDA, MDD, HC, TGA, and others as applicable); EU Competent Authorities; Notified Bodies;	Quality Assurance (Refer to Adverse Event Notification guidelines on the web pages of various regulatory bodies in countries where we market our products to)	As indicated on CP207 – Medical Product Complaint Handling
Defect or failure to comply (Nuclear Containment Monitors and spare parts thereof)	The Regional NRC and the Utilities	Quality Assurance (Refer to CP205 and to the current version of 10CFR21 regarding reporting requirements)	As indicated on CP205.



**PRACTICES**

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 39 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

**ISO 13485: 2016**

**TABLE OF CONTENTS**

**INTRODUCTION**

**SCOPE**

**PURPOSE**

**CONTROL OF MANUAL**

**QUALITY SYSTEM CROSS-REFERENCE MATRIX**

**QUALITY SYSTEM ISO 13485:2016**

**CLAUSE 4: QUALITY MANAGEMENT SYSTEM**

**CLAUSE 5: MANAGEMENT RESPONSIBILITY**

**CLAUSE 6: RESOURCE MANAGEMENT**

**CLAUSE 7: PRODUCT REALIZATION**

**CLAUSE 8: MEASUREMENT, ANALYSIS, AND IMPROVEMENT**


**ADDENDUM A: MEDICAL DEVICE REGULATORY COMPLIANCE**

**ADDENDUM B: INTERNAL CONTROLS-COSO FRAMEWORK**

**(MANAGED BY THE PLANT CONTROLLER)**

**ADDENDUM C: REGULATORY/REGISTRAR/NOTIFIED BODY CONTACT INFORMATION**

**ADDENDUM D: OBLIGATION TO INFORM**

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 40 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

## 1.0 INTRODUCTION

This Manual document our practices to meet the requirements of the Quality Management System of Teledyne Analytical Instruments (hereinafter called “company”, “our”, “organization”, or “facility”), and demonstrates our ability to consistently provide products and services that meet customer and applicable statutory/regulatory requirements. This manual outlines the steps towards the effective application of the Quality Management System, in route to enhancing customer satisfaction.

The company’s principal business is the manufacture of process gas and liquid analytical instruments, and medical devices categorized as sensors, analyzers, and custom-engineered systems. Reference is made to our web pages at [www.teledyne-ai.com](http://www.teledyne-ai.com) for a comprehensive list of our technologies and products, and various industries in that we market our products.

See page 2 for our Quality Policy statement.


## 2.0 SCOPE

This Manual forms the framework of our Quality Management System. This practice defines the quality system implemented at our facility and complies with the requirements of various Standards, Directives, and Regulations such as ISO 9001:2015 (compliance is without exclusion), ISO 13485:2016 (compliance is without exclusion), ISO 80079-34, ATEX Directive 2014/34/EU, Directive 2007/47/EC Including MDR EU 2017/745, Article 120 and 21CFR820

## 3.0 PURPOSE

- The purpose of this Quality Manual is to describe and document the Quality System implemented within our company.
- This manual is the central source of general practices and procedures that authorize and govern the creation of subsidiary quality systems-related documentation and activities.
- This manual provides comprehensive evidence to customers, suppliers, and employees that the company is committed to establishing and maintaining acceptable levels of Quality in its products and services.



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 41 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

#### 4.0 CONTROL OF MANUAL

Control and revision of the Quality Manual is conducted in accordance with the document control procedures described in Clause 4.2.3 - Control of Documents. Quality Manuals that are issued to customers and to others outside the facility are marked as UNCONTROLLED. Changes to the Quality Manual may be initiated by any employee when it is determined that change is necessary to improve the Quality Management System toward achieving quality objectives. Implementation of any suggested changes to the Quality Manual will need the approval of the Site Lead, the Management Representative, and the VP/General Manager. Any significant changes that would cause noncompliance with the Quality System will require notification to the affected regulatory or registration agency.



**PRACTICES**

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**


**PAGE: 42 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

**QUALITY SYSTEM CROSS-REFERENCE MATRIX**

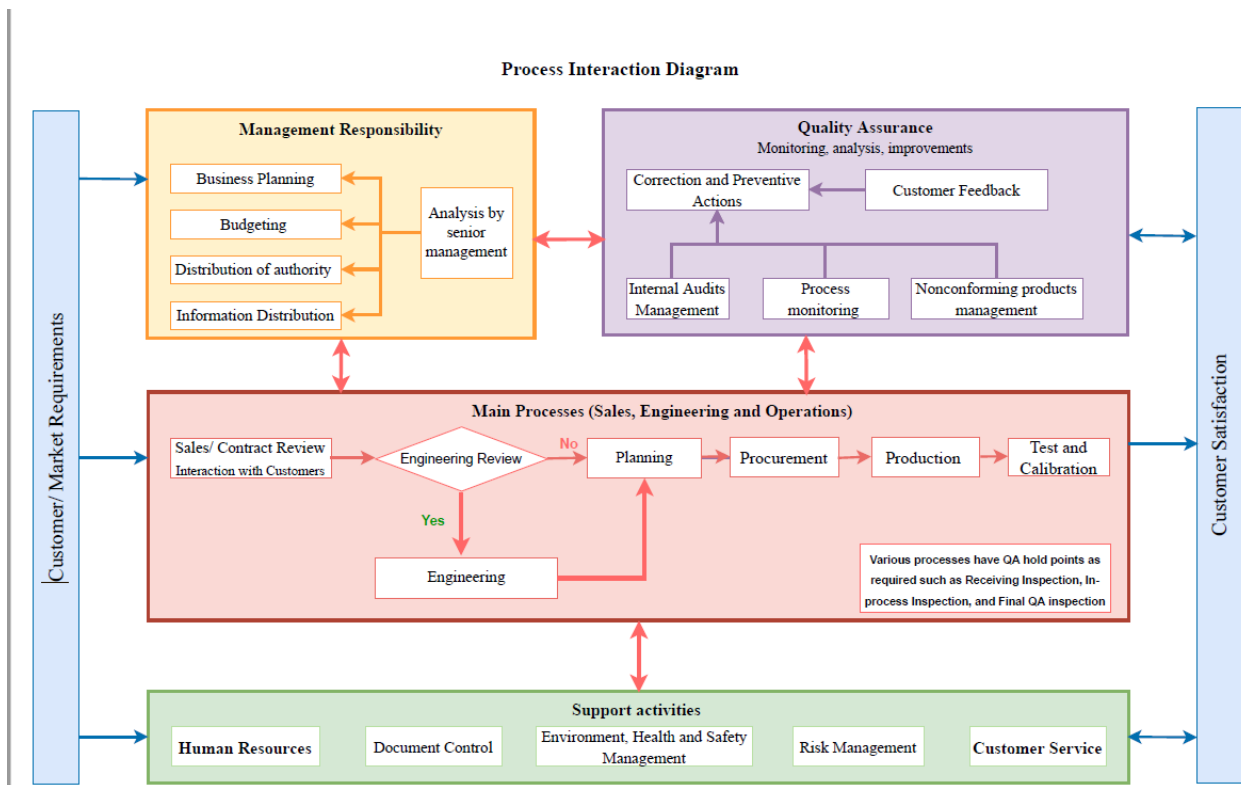
ISO 13485:2016 Clauses & CP100 Addendums	Reference Documents	ISO 9001:2015 Clauses	Medical Devices FDA 21CFR820	EU MDD 93- 42/EEC, as Amended by Directive 2007/47/EC
4.1	CP230	4.4	820.20	Annex II-3.4
4.2	CP202,204,218,230. DC403,415,417,423,424,616	4.3, 7.5, 7.5.1, 7.5.2, 8.5.6	820.20, 820.40, 820.180, 820.186	Annex II-3.2, Annex II- 3.4
5.1	CP100	4.1, 5.1, 5.2	820.5, 820.20	
5.2	SA400	5.1		
5.3	CP100	5.2	820.5, 820.20	
5.4	CP100,230	6.1, 6.2, 6.3, 8.5.6	820.5, 820.20	Annex II-3.4
5.5	CP100	5.3, 7.4	820.5, 820.20	
5.6	CP100	9.3	820.5, 820.20	
6.1	CP100	4.2, 7.1, 7.1.1	820.5, 820.20	
6.2	CP100,200	7.1, 7.1.2, 7.1.6, 7.2, 7.3	820.5, 820.20, 820.25	
6.3	MS400,401,402; PD400,401,402; SD400,401	7.1.3	820.70	
6.4	MS400,401,402; PD400,401,402. SD400,401	7.1.4	820.70	
7.1	CP230; QA401,402,404,405,406,413. TD402	6.1, 8.1	820.20, 820.80	Annex II-3.4
7.2	ED400; SA400; SR401	8.2-8.2.4, 8.5.5	820.30	
7.3	ED400; SR401	8.3-8.3.6, 8.5.6	820.30	Annex II-3.4
7.4	PU400,402; QA401,402,404,405,406,413; TD402	8.4-8.4.3	820.50	
7.5	CP228,229,231; CS400,402; MS400,401,402; PD400,401,402; QA401,402,404,405,406,413; SD400,401; TD402,403; WH400,401,402,405,406,411	8.5-8.5.5	820.60, 820.65, 820.70, 820.86	Annex IV-6.4,
7.6	QA411,412	7.1.5	820.72	
8.1	CP219; QA401,402,404,405,406,413; TD402	9.1, 9.1.1	820.80, 820.250	
8.2	CP219; QA401,402,404,405,406,413,417; TD402	8.6, 9.1, 9.9.1, 9.1.2, 9.2	820.80	
8.3	CP223; QA414,415	8.7, 10.1, 10.2	820.90	
8.4	CP219	9.1.3	820.250	
8.5	CP100; QA421	6.1, 10.1, 10.2, 10.3	820.5, 820.20, 820.100	Annex II-3.1
Addendum A	Medical Devices-CP 207, 223	(ISO 13485)8.1, 8.2, 8.4	820.198	
Addendum B	COSO Framework (Finance)-CP 250			
Addendum C	Contact Information			
Addendum D	Obligation to Inform			
	CP251 - CMDR			

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS <i>Everywhere you look™</i>	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 43 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 4**

**QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES**


**4.1 GENERAL**



This Quality Manual describes the quality system implemented and maintained at our facility that, amongst others, complies with the requirements of various standards mentioned elsewhere in this document.


Key processes determined for incorporation into our Quality Management System and their interactions are outlined below. These require the application of a risk-based approach to the control of the appropriate processes. These are monitored, and where applicable, measured, and analyzed.

- Management System
  - Administered by the Executive Management, this process defines the Quality Policy and sets Quality Objectives and is responsible for communicating these to all ranks within

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 44 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

the company. This process is also responsible to ensure the general availability of resources and information necessary to support the company operations.

- Executive Management, with assistance from Departmental Management, has the overall responsibility to implement actions necessary to achieve planned results and maintain the effectiveness of the company processes.
- Sales/Contract Review
  - Input to this process is in the form of inquiries, requests for quotation or purchase orders/contracts from the customers. Each inquiry or contract received is reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. The results from this process will be the inputs to either the Engineering or Operations functions.
- Engineering
  - This process involves all research and sustaining engineering activities. Sales and Marketing driven inputs to this process result in products engineered to specific customer needs or designed to fulfill discovered market opportunities.
- Operations
  - This process encompasses the Document Control, Production Control, Purchasing, Warehousing, Manufacturing, Test & Calibration, and Shipping functions of the company. This complex process has inputs typically coming from either the Sales or Engineering functions into the Production Control function, which then forms the feeder to the remainder of the Operations process. The typical final output from the Operations process is the manufactured Product. The Product will be verified by the Quality process to ensure compliance to the customer/regulatory/notified body requirements prior to forwarding the Product to the Shipping function for shipment.
  - Control of the products/processes outsourced will be administered as outlined in the Purchasing Department procedures.
- Quality Assurance
  - This process is responsible to ensure continued compliance of the company's Quality System to various standards adopted by the company.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 45 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>
<ul style="list-style-type: none"> <li>○ This process has the responsibility to ensure that the requirements of the customers, regulatory bodies, notified/registrar bodies, and of the company’s internal procedures are in harmony and are reflected in our products, and in the event of any nonconformance, take necessary steps, including Corrective &amp; Preventive actions, to correct such non-conformance.</li> <li>○ This process is responsible to maintain continued compliance with the company’s Quality System through periodic internal audits.</li> <li>○ The input to this process is from customers, operations, and regulatory authorities. While the output of this process is management review, process monitoring, customer satisfaction, and regulatory compliance.</li> </ul> <ul style="list-style-type: none"> <li>▪ Customer Service <ul style="list-style-type: none"> <li>○ This process is responsible for all product-related field issues. This process also maintains metrics to measure the company’s performance related to post-sales customer feedback and vigilance in route to maintaining continual customer satisfaction.</li> </ul> </li> <li>▪ Human Resources <ul style="list-style-type: none"> <li>○ This process is responsible to ensure that the personnel performing work affecting product quality and related supporting functions are competent, based on appropriate education, training, skills, and experience.</li> </ul> </li> </ul> <p><b>4.2 DOCUMENTATION REQUIREMENTS</b></p> <p><b>4.2.1 GENERAL</b></p> <p>This section incorporates by reference our Mission, our Quality Policy and Quality Objective as illustrated elsewhere in this Quality Manual document.</p> <p>The Quality System is structured into three levels of documentation:</p> <ol style="list-style-type: none"> <li>1. Level One is documented in the form of a Quality Manual, which contains the Practices of the company.</li> <li>2. Level Two documents are the departmental procedures that are referenced in the Quality Manual, which implement the quality system and quality policy</li> </ol>		



# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**


**PAGE: 46 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

3. Level Three documents are specific departmental work instructions utilized in most cases to carry out a specific task.

Records in support of the Quality System are maintained as outlined in section 4.2.4.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 47 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

#### 4.2.2 QUALITY MANUAL


This entire document forms the framework of our Quality Management System and is hereby incorporated as our Quality Manual. As described elsewhere, this Manual establishes the Scope of our Quality Management System and outlines various procedures as Reference Documents in support of our Quality Management System.

#### 4.2.3 MEDICAL DEVICE FILE

For each Medical Device type or medical device family, the company shall establish and maintain a device master record (technical file) containing all technical information about the device. Where applicable, the technical file will also include copies of manufacturing processes and installation/maintenance guidelines.

#### 4.2.4 CONTROL OF DOCUMENTS


- Documents applicable to the Quality System defined in this Quality Manual are subject to review for adequacy, update, and approval by authorized personnel prior to issue.
- Documentation will be controlled to ensure the availability of current, pertinent, and relevant information to all functioning organizations at the points of use.
- Documentation changes are reviewed by the Configuration Control Board (CCB). CCB representatives have access to pertinent information needed to approve/reject changes.
- A Master List of all documents applicable to this Quality System has been established and is maintained and readily available to preclude the use of invalid and/or obsolete documents.
- Documents of external origin necessary to comply with the Quality Management System, such as Standards documents, are under document control.
- Obsolete documents are removed to prevent inadvertent use. Documents that are retained for legal or historic purposes are labeled “obsolete” to ensure they are not mistakenly used. For critical equipment such as nuclear containment monitors and medical devices, obsolete documents will be maintained for at least the lifetime of the equipment.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 48 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

#### 4.2.5 CONTROL OF RECORDS

- Documented procedures have been implemented for the identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.
- Records demonstrating conformance to specified requirements and the effective implementation of this quality management system are maintained.
- Records will be legible, retrievable, stored, and maintained in a safe, secure environment to prevent damage, deterioration, and loss.
- Quality Records retention times are incorporated into the Quality Manual through reference to the Control of Quality Records Procedure CP204.



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 49 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 5**

**MANAGEMENT RESPONSIBILITY**

**5.1 MANAGEMENT COMMITMENT**

In our quest to continually improve the quality of our products and to achieve the goals of Customer Satisfaction and applicable statutory and regulatory compliance, the Executive Management of the company is committed to the summary implementation of the Quality Management System in accordance with the framework presented in this Quality Manual.

This objective is achieved through:


- Clear and periodic communications with the management team and the employees regarding the importance of meeting the requirements of the customers, standards, regulatory agencies, registrar, and notified bodies and of our Quality Management System. Partial list of forums used for such communications are:
  - Management Review Meetings
  - Staff Meetings
  - Company All-hands Meetings
- Establishment of the Quality Policy and execution of the Quality Objectives.
- Ensuring that requisite resources - qualified personnel, equipment, and facility - are in place.

**5.2 CUSTOMER FOCUS**

Each contract or order that is received is reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. Our capabilities are assessed in relation to the customer requirements to determine our ability to accept the order. The review will also include any statutory and regulatory requirements related to the product or order.

If the customer’s requirements are different from our capabilities, then those differences are communicated to the customer and any issues resolved prior to our accepting the order.

The Customer Service function will address the post-sales product related field issues along with maintaining relevant metrics to measure/monitor company’s performance related to post-sales customer feedback and vigilance in route to maintaining continual customer satisfaction.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 50 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

### 5.3 QUALITY POLICY

The Top Management of the company is committed to continual improvement of the quality of our products, satisfaction of our customers, and compliance with applicable statutory/regulatory requirements. Management is also committed to complying with the requirements and maintaining the effectiveness of our Quality Management System.

This Policy is communicated to all ranks within the organization and is periodically reviewed for its continued suitability.

### 5.4 PLANNING


#### 5.4.1 QUALITY OBJECTIVES

We assess the success of our Quality Objectives through frequently collected measurable data that are discussed during our periodic Management Review sessions. The specific and measurable Quality Objectives are:

- First Pass Yield
  - Instruments
  - Spares
- Sensor Production Yield
- Price of Nonconformance
  - Cost of Scrap
  - Cost of Rework
  - Cost of Warranty
- On-Time Delivery
  - To our customers
  - From our Suppliers
- Linear Shipment

#### 5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

Through the provisions and processes mentioned under the Clause 4.1 of this document, augmented by the company/departmental procedures and work Instructions, the top management of the company ensures that the quality management system complies with the meets the quality policy and strives to achieve the goals set for quality objectives.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 51 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

Configuration Control Board authorization will be required before implementing any changes to the quality system. Changes to this quality manual will require approval by the top management.

## 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

### 5.5.1 RESPONSIBILITY AND AUTHORITY

This practice defines the company’s responsibility, authority, and interrelationship with all personnel.

The organization is structured functionally with all the department heads reporting directly to the VP/General Manager. The Human Resources and the Finance functions have an indirect reporting responsibility to General Manager.

Independent of his/her position, any individual in the company has the authority to stop the product that he/she feels does not meet quality requirements.

All employees are responsible for fulfilling the quality system requirements for their respective areas. All employees have the authority to identify problems and to initiate, recommend or provide solutions through their department supervisor, or manager.

Quality Assurance Department principally has the responsibility to identify and record non-conformances, and the authority to initiate action to prevent noncompliance issues to the product, process, and quality system.

The Material Review Board (MRB) (consisting of representatives from the Production, Engineering, and Quality Assurance Departments) is responsible for recommending, providing, and implementing solutions to correct and prevent non-conformances.



# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 52 OF 76**


**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

## ORGANIZATIONAL CHART

Refer to the link below for the current Organizational Chart

<L:\DEPT\QA\QA\ORGANIZATION CHART 2022\TAMS ORG CHART 12.2022, MR, M. KHAN.PDF>

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 53 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

## 5.5.2 MANAGEMENT REPRESENTATIVE

The Company's Management Representative reports to the top management and is assigned with the responsibility and the requisite authority to ensure that the processes required to administer the quality management system are established and implemented.

Management Representative is also responsible for and has the appropriate authority to ensure compliance with the requirements of various Standards/Regulatory/Registrar/Notified bodies.

Management Representative will ensure the promotion of regulatory and customer requirements and is responsible for reporting to the company's management on the performance of the Quality System and any recommended changes and improvements to the system.

Management Representative: As appointed by the Head of the Organization, VP of Operations/ QA. See company organizational chart for current appointment.

## 5.5.3 INTERNAL COMMUNICATION


The top management will periodically discuss with the company's management team and the employees the importance of meeting the requirements of the customers, standards, regulatory agencies, registrar, and notified bodies and of our Quality Management System.

## 5.6 MANAGEMENT REVIEW

### 5.6.1 GENERAL

Top Management will review the Quality System, Policy & Objectives with the company's management team on an annual basis, as a minimum and not exceed 14 months, to ensure its continued adequacy, suitability, and effectiveness, and to discuss opportunities for improving the quality system.

The certified product liaison under the ATEX directive, i.e., an authorized person, must attend this review.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 54 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>


### 5.6.2 REVIEW INPUT

The review shall address the following as a minimum:

- Action items from the previous management review meetings.
- The audit program (internal/external) – Results of previous audits, and any quality system improvement opportunities resulting from the audits.
- Status of Corrective & Preventive Actions (internal/external)
- Status of the third-party certified products.
- Product conformance profiles and cost of quality discussions.
- Internal (manufacturing) and external (supplier) operational performance – Opportunities and challenges.
- Internal and external (e.g., customer) feedback on product and market performance trends, and recommendations to process improvements.
- The quality system effectiveness with respect to the adopted standard(s).
- Any recommendations for improving the Quality Management System.
- Any new or revised statutory or regulatory requirements.

### 5.6.3 REVIEW OUTPUT

The Management Review is to facilitate the necessary actions and allocate the resources to improve the quality system, processes, and products to comply with customer and statutory/regulatory body requirements.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<b>PRACTICES</b>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 55 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 6**

**RESOURCE MANAGEMENT**

**6.1 PROVISION OF RESOURCES**

Company’s Management shall identify resource requirements and provide adequate resources to implement the Quality Management System and maintain its effectiveness, enhance customer satisfaction, and meet regulatory and customer requirements. The term “resources” is used in this paragraph to include Human, Facility, and Environmental resources.

**6.2 HUMAN RESOURCES**

**6.2.1 GENERAL**

As noted above, the company’s Management shall identify the human resource requirements and provide adequate resources to enhance customer satisfaction and meet regulatory and customer requirements. This includes the assignment of trained personnel for management, the performance of work, and verification activities including internal quality audits.


**6.2.2 COMPETENCE, TRAINING, AND AWARENESS**

This practice defines the provisions made within the company to ensure that all personnel is adequately trained for the tasks that they are required to undertake.

Documented procedures have been implemented to identify training needs and the training of all personnel performing activities affecting product quality and conformity. The objective is to ensure the employees are aware of the importance of, and how they contribute to, their activities.

Personnel performing specific assigned tasks are qualified based on education, experience, and/or training.

Records of training are maintained.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 56 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

### 6.3 INFRASTRUCTURE

The top management has allocated and maintained the necessary infrastructure in keeping with the strategic growth plans for the company. The infrastructure development includes building management, workspace development, conformity to product requirements, preventing product mix-up, office/process equipment, communications equipment, information systems, and utility maintenance. The adequacy of the company’s infrastructure will be reviewed, and changes are made as needed to meet the growth initiatives.

### 6.4 WORK ENVIRONMENT AND CONTAMINATION CONTROL

#### 6.4.1 WORK ENVIRONMENT


The company has identified and planned the production and servicing processes that directly affect product quality and shall ensure that these processes are carried out under a controlled environment which includes:

- Documented procedures defining the method of production.
- Use of suitable production equipment and a suitable working environment to achieve product conformity.
- Criteria for workmanship as defined in the written standards, representative samples, photos, and/or illustrations.
- Manufacturing equipment maintenance plans to ensure continuing process capability.
- Procedures for Electrostatic Discharge Protection and Personal Protection Equipment to help eliminate any adverse effects due to interaction amongst the personnel, product and the work environment.

#### 6.4.2 CONTAMINATION CONTROL

The company has identified and planned the processes for the control of contamination that directly affect product quality and personnel. Medical devices supplied by the company are not sterile devices nor or they designed to be sterilized in use.



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 57 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 7**

**PRODUCT REALIZATION**


**7.1 PLANNING OF PRODUCT REALIZATION**

In keeping with the quality management system, the company has adopted the following plan and developed processes and procedures for risk management needed to manufacture the product.

- Preparation of Quality Plans (Route Sheets).
- Identification and acquisition of controls, processes, equipment, fixtures, resources, and training that may be required.
  
- Ensuring the compatibility of the design, processes, inspection, and testing procedures and applicable documents.
- Ensuring that inspection and testing documents are updated as needed.
- Identification of verification, validation, monitoring, and measurement requirements that meet the known state of the art to allow for the development of adequate techniques.
- Identification of required and/or necessary inspection and test operations in the product flow to achieve product acceptance.
- Inspection and test criteria shall be clarified, particularly those criteria that may be subjective.
- Identification and preparation of quality records (For medical devices this includes the device master file).
  - Files shall be maintained defining the type and/or model of the Medical Device, corresponding product specifications, manufacturing process methods, installation, and service, as applicable.
- Any other documentation required by Domestic or International regulations.

Documented procedures have been implemented for inspection and testing activities to verify that specified requirements are satisfied. Records of the required inspection and testing are defined in the procedures.

The internal audit process verifies the effectiveness of the product realization plan.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 58 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**7.2 CUSTOMER-RELATED PROCESSES**

- 7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT,**
- 7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT AND**
- 7.2.3 COMMUNICATION**

Requests for proposals or contracts or orders are reviewed to ensure that the customer requirements, both technical and commercial, are adequately defined and documented. Our capabilities are assessed in relation to the customer requirements to determine our ability to accept the order. The review will also include any statutory and regulatory requirements related to the product or order and any additional requirements determined by TAI.

If the customer’s requirements are different from our capabilities, then those differences are communicated to the customer and any issues are resolved prior to our accepting the order.

Amendments to contracts are identified and revised requirements are distributed to appropriate functions. When applicable, contract amendments will be evaluated to ensure compatibility with registrar/notified body certifications.

The proposal, product brochure, or order acknowledgment will serve as the document to confirm the requirement of the customer.


The records of the review will be maintained.

The Customer Service and Quality Assurance functions will perform the post-sales product-related customer communications along with maintaining relevant metrics to measure/monitor the company’s performance related to post-sales customer feedback and vigilance, including handling customer complaints and issuance of any advisory notices.

**7.3 DESIGN AND DEVELOPMENT**

- 7.3.1 GENERAL**

Documented procedures have been implemented to for design and development.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b>  <b>QUALITY MANUAL</b>	<b>PAGE: 59 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**7.3.2 DESIGN AND DEVELOPMENT PLANNING**

Plans are prepared for each design and development activity. The plans describe or reference these activities, including verification and/or validation actions and reviews deemed appropriate for each design and development stage. The plan also assigns responsibilities to qualified employees for the completion of the activities, including the design transfer activities prior to production. The plans are updated as designs evolve. Resource and Technical Interfaces between different departments of the company that provide input into the design process are documented, transmitted, and reviewed.

**7.3.3 DESIGN AND DEVELOPMENT INPUTS**

All design requirements such as functional/performance, statutory/regulatory, and safety requirements and statutes related to the product design and intended use are identified, documented, reviewed, and approved. Incomplete, ambiguous, and conflicting requirements are resolved with personnel imposing these requirements. When applicable, the design input process will take into consideration the results of


any contract review activities, requirements of any statutory/regulatory bodies, the result of risk management study, and usability.

**7.3.4 DESIGN AND DEVELOPMENT OUTPUTS**

All design outputs are verified/validated, documented, and maintained against the design input requirements. Design output requirements shall meet or exceed the input requirements, contain, or reference acceptance criteria and identify those characteristics that are crucial to product safety and the safe and proper functioning of the product. Design output documents are reviewed for completeness prior to release to purchasing, production, and service functions. Records of the activity are maintained.

**7.3.5 DESIGN AND DEVELOPMENT REVIEW**

At appropriate stages of design and before product release, formal design reviews are conducted in accordance with the Design and Development Planning. Representatives of all functions involved in that stage of the design, competent independent observer, and others as deemed necessary will participate in these reviews which will include the identification of the design under review, representatives, and date of review. Review records are maintained.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 60 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**7.3.6 DESIGN AND DEVELOPMENT VERIFICATION**

Verification of design is conducted at appropriate stages to ensure that the design stage output meets the design stage input requirements. These verification measures are recorded.

**7.3.7 DESIGN AND DEVELOPMENT VALIDATION**

Design validation is performed to ensure that the product conforms to defined user needs and/or requirements. Validation shall be completed prior to production activities. Where necessary, such validation shall entail off-site studies such as EMI/RFI studies, clinical trials, and the like. The validation records are maintained.

**7.3.8 DESIGN AND DEVELOPMENT TRANSFER**

Design changes and modifications are reviewed and approved by authorized personnel prior to release to operations.

**7.3.9 CONTROL OF DESIGN AND DEVELOPMENT CHANGES**

Before implementation, design changes and modifications are identified, documented, reviewed, and approved by authorized personnel. Changes effect should be made on products in process and on the output of risk management and product realization processes and the significance of a design and development change.

**7.3.10 DESIGN AND DEVELOPMENT FILES**


Design and development changes for each medical device is recorded and maintained.

**7.4 PURCHASING**

**7.4.1 PURCHASING PROCESS**

The suppliers are selected based on their ability to meet company’s Quality System requirements.

Measures of evaluation, selection, and re-evaluation of sub-contractors are documented and shall include one or more of the following:

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 61 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

- Type of product
- Evaluation of the sub-contractor’s previous inspection history.
- Sub-contractor’s technical and quality capability as determined by an audit of the sub-contractor’s facility and quality system.
- Sub-contractor’s achievement of an internationally approved quality system.
- The impact of the supplied product in meeting the quality of the final product.
- The impact of the supplied product with the risk associated with a medical device.

Records of approved suppliers are maintained.

#### 7.4.2 PURCHASING INFORMATION

Purchase Orders and documents containing requirements for products being ordered shall include, as applicable:

- Type, class, grade, or other precise identification.
- Positive identification, including titles, numbers, revision levels, special requirements, and instructions, including approval or qualification of product, procedures, traceability (critical components and materials), process equipment, and personnel.
- Applicable Quality System standards.


Procurement documents are reviewed and approved for adequacy of the specified requirements prior to release. Copies of the purchase orders are maintained.

#### 7.4.3 VERIFICATION OF PURCHASED PRODUCT

The right to verify materials at source, when necessary, will be specified in the purchase document.

Where required by contract, the right of access to the company’s and sub-contractor facilities/records for product verification will be made available.

Verification of the product by the customer shall not be used by the company as evidence of effective control of quality by the sub-contractor.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 62 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

Verification of the product by the customer does not absolve the company of the responsibility to provide an acceptable product, nor does it preclude subsequent rejection by the customer.

No purchased product shall be used until it has been inspected, or otherwise verified as conforming to specified requirements or considered dock-to-stock based on vendors' history. Activity records are maintained.

## 7.5 PRODUCTION AND SERVICE PROVISION

### 7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

These practices define the way in which the manufacturing and servicing processes will be controlled, and where required,

The company has identified and planned the production and servicing processes that directly affect product release, product quality, delivery, and post-sales activities, and shall ensure that these processes are carried out under controlled infrastructure which includes:

- Documented procedures and work instructions defining the method of production.
- Use of suitable production, monitoring, and measuring equipment and a suitable working environment to achieve product conformity.
- Monitoring and control of the suitable process and production parameters.
- The approval of processes and equipment, as appropriate.
- Criteria for workmanship as defined in written standards, representative samples, photos, and/or illustrations.
- Manufacturing equipment with maintenance plans to ensure continuing process capability.
- Protection of products after final inspection and test. Where required, this protection will be extended to the delivery to the destination.
- Servicing process control, utilizing post-production activities or customer feedback. Records of any factory service performed shall be maintained.
- Validation of any software.

Any process that cannot be verified by subsequent inspection and testing will be carried out by qualified operators and/or the process parameters will be controlled and monitored continuously and revalidated, as necessary, to ensure specified requirements are met. The requirement for qualification of any operation or operator will be documented and records maintained.

# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 63 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

## 7.5.2 NOT APPLICABLE TO ISO 13485:2016 STANDARD

Medical devices supplied by the company are not sterile devices nor or designed to be sterilized in use. Their cleanliness is not significant in use. Hence, the referenced clause of the standard is not applicable to the company.

## 7.5.3 NOT APPLICABLE TO ISO 13485:2016 STANDARD

Devices supplied are oxygen analyzers, monitors, and sensors, requiring no factory-assisted installation.

## 7.5.4 SERVICING ACTIVITIES

The company has identified and planned the servicing processes that directly affect post-sales activities and shall ensure that these processes are carried out under controlled infrastructure. Records of any factory service performed shall be maintained

## 7.5.5 NOT APPLICABLE TO ISO 13485:2016 STANDARD


Not applicable as the devices supplied are not sterile devices.

## 7.5.6 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

These practices define the way in which the manufacturing and servicing processes will be validated.

The company has identified and planned the production and servicing processes that directly affect product release, product quality, delivery, and post-sales activities, and shall ensure that these processes are carried out under controlled infrastructure which includes:

- Documented procedures and work instructions defining the method of production.
- Use of suitable production, monitoring, and measuring equipment and a suitable working environment to achieve product conformity.
- Monitoring and control of the suitable process and production parameters.
- The approval of processes and equipment, as appropriate.
- Criteria for workmanship as defined in written standards, representative samples, photos, and/or illustrations.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 64 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

- Manufacturing equipment with maintenance plans to ensure continuing process capability.
- Protection of products after final inspection and test. Where required, this protection will be extended to the delivery to the destination.
- Servicing process control, utilizing post-production activities or customer feedback. Records of any factory service performed shall be maintained.
- Validation of any software.

Any process that cannot be verified by subsequent inspection and testing will be carried out by qualified operators and/or the process parameters will be controlled and monitored continuously and revalidated, as necessary, to ensure specified requirements are met. The requirement for qualification of any operation or operator will be documented and records maintained.

**7.5.7 NOT APPLICABLE TO ISO 13485:2016 STANDARD**

Not applicable as the devices supplied are not sterile devices.

**7.5.8 IDENTIFICATION**

This practice defines how product identification will be maintained.

The product shall be identified through all stages of production to delivery. Identification will be provided through physical identification (marking or tags) wherever practical. When physical identification is impractical, appropriate means of identification will be used.


**7.5.9 TRACEABILITY**

This practice defines how product identification and traceability will be maintained.

The product shall be identified through all stages of production to delivery. Identification will be provided through physical identification (marking or tags) wherever practical. When physical identification is impractical, appropriate means of identification will be used.

When traceability is a specified requirement, the company maintains procedures that define the method used for the identification of the individual product or lot to specific documentation such as purchase order, work order and/or sales order number. This identification will be recorded.



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 65 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

The inspection and test status of the product are identified by suitable means (e.g., monitoring, measurement), which indicate the conformance or nonconformance of the product regarding inspections and tests performed. Records of inspection and test are maintained.

**7.5.9.2 NOT APPLICABLE TO ISO 13485:2016 STANDARD**

Not applicable as supplied devices are not implantable devices.

**7.5.10 CUSTOMER PROPERTY**

The company ensures that any customer-supplied product or information for incorporation into the final product is identified, verified, stored, and maintained. If such a property is inadvertently lost, damaged, or otherwise found unsuitable for use, this shall be reported to the customer and records shall be maintained.

**7.5.11 PRESERVATION OF PRODUCT**

Documented procedures have been implemented for the identification, handling, storage, packing, preservation, and delivery of the product.

The product is handled in such a way as not to damage the product.


Designated storage areas are used to prevent damage to the product pending use or delivery.

The product will be packaged and marked to ensure product quality and identification requirements are maintained.

The product is preserved through appropriate methods to ensure ongoing fitness for use. Product subject to deterioration with age or with a specified shelf life will be controlled.

**7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT**

Documented procedures have been implemented to control, calibrate, and maintain inspection, measuring, and test equipment used to demonstrate the conformance of products to specified requirements.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 66 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

The inspection, measuring, and test equipment will be used in a way that is consistent with the measurements it is required to make.

Inspection, measuring, and test equipment are identified, calibrated, and adjusted at prescribed intervals against certified equipment having known relationships to national or international standards. Where no such standards exist, the basis for calibration shall be documented.

Steps are taken to ensure that the environmental conditions are suitable when calibration of inspection, measurement, and test equipment is performed.

Inspection, measuring, and test equipment are tracked by equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and action to be taken when the results are unsatisfactory.


Test software and hardware are tested on a regular basis to ensure continuing suitability. Records or such checks are maintained.

Where required by customers, technical data on inspection, measuring, and test equipment shall be available.

Inspection, measuring, and test equipment have their calibration status clearly identified and verifiable by the operator/inspector.

When inspection, measuring, and test equipment are found to be out of calibration, an evaluation shall be made and documented to address the product tested on the suspect inspection, measuring, and test equipment.

Records for calibration of inspection, measuring, and test equipment is maintained. Inspection, measuring, and test equipment are stored in such a way that fitness for use is maintained and safeguarded against adjustments that would invalidate calibration.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<b>PRACTICES</b>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 67 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**CLAUSE 8**

**MEASUREMENT, ANALYSIS AND IMPROVEMENT**

**8.1 GENERAL**

As discussed elsewhere, through the provisions and processes mentioned under Clause 4.1 of this document and augmented by the company/departmental procedures and work Instructions, the company ensures that proper monitoring, measurement, analysis, and improvement processes are established to ensure conformity to and maintain/improve the effectiveness of the quality management system.

Documented procedures have been implemented for inspection and testing activities to verify that specified requirements for the product are satisfied. Records of the required inspection and testing are defined in the procedures.

Statistical techniques are employed where applicable for establishing, controlling, and verifying process capability and product characteristics. The key performance indicator (KPI) data are collected and analyzed for trends and identification of improvement opportunities. The data will be distributed for management and factory personnel knowledge and awareness.


**8.2 MONITORING AND MEASUREMENT**

**8.2.1 CUSTOMER SATISFACTION AND FEEDBACK**

As part of the KPI data, the company will gather post-sales product performance and customer feedback data for analysis and possible implementation of improvements to ensure that the company has met the customer requirements and has achieved continued customer satisfaction. The aspects of customer perception on our performance and customer satisfaction are crucial to the survival of the company. These performance indicators are verified and validated during the pre-sales and post-sales customer visits undertaken by various personnel of the company.

**8.2.2 COMPLAINT HANDLING**

Documented procedures have been implemented to handle customer complaints in a timely manner. Disposition of the customer complaint may identify the need for any

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 68 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

failure analysis that may lead to corrective/preventive actions. Records shall be maintained.

**8.2.3 REPORTING TO REGULATORY AUTHORITIES**

Documented procedures have been implemented to handle the need for any reporting to the Regulatory authorities. Records shall be maintained.

**8.2.4 INTERNAL AUDIT**

This practice defines the conduct of internal quality audits. The intent is to monitor and measure quality system processes and demonstrate the ability of the system to achieve planned results.

Documented procedures have been implemented for the performance of regularly scheduled internal quality audits to verify that activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Audits are planned and scheduled based on the status and importance of the activity being audited. Individuals who do not have direct responsibility for the activities being audited perform these audits.

Audit results will be recorded and reported to personnel responsible for the activity being audited. The management personnel responsible for the area will take timely corrective action on deficiencies noted during the audit.


Should a nonconformity discovered during the internal audit be significant as to affect the product quality or safety if not immediately corrected, the management of the area being audited shall ensure that immediate and necessary corrections are implemented, and then determine the cause for such nonconformity and take corrective actions to prevent occurrence.

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

Results of internal audits shall comprise part of the management review.

**8.2.5 MONITORING AND MEASUREMENT OF PROCESSES**

As discussed elsewhere, through the provisions and processes mentioned under Clause 4.1 of this document, the company ensures that proper monitoring,

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 69 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

measurement, analysis, and improvement processes are established to ensure conformity to and improve the effectiveness of the quality management system.

When the inspection, statistical data (KPI), or the internal audit processes discover that the planned results are not achieved, correction through an ECO or corrective action, as appropriate, will be taken to ensure conformity to the plan.

### 8.2.6 MONITORING AND MEASUREMENT OF PRODUCT

No product shall be used until it has been inspected, or otherwise verified as conforming to specified requirements. Verification of the specified requirements is performed to the Quality Plan and/or documented procedures.

In-process inspection and test steps are defined in the Quality Plan and/or procedures.


All Final Inspection and Testing will be completed in accordance with the Quality Plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

In addition to the inspection of finished product characteristics, checks will be made to establish that all previous inspections and tests have been carried out with satisfactory results.

The product will not be released until all required inspections and tests determine whether the product has conformed to requirements or deviations have been approved by the customer or relevant authority.

Records of inspection and test are maintained. These records clearly show whether the product has passed or failed the inspections and/or tests defined in documented criteria. Products that fail any inspection and/or test will be handled in accordance with the procedure for the control of nonconforming products.

Records are also maintained of the individuals having authority and responsibility to release products.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 70 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**8.3 CONTROL OF NONCONFORMING PRODUCT**

**8.3.1 GENERAL**

**8.3.2 ACTIONS IN RESPONSE TO NONCONFORMING PRODUCT DETECTED BEFORE DELIVERY**

**8.3.3 ACTIONS IN RESPONSE TO NONCONFORMING PRODUCT DETECTED AFTER DELIVERY**

Documented procedures have been implemented to ensure that a product that does not conform to specified requirements is prevented from unintended use, installation, or delivery.

The system for the control of the nonconforming product, detected before and after delivery, provides for the identification, documentation, evaluation, segregation, disposition of nonconforming products, and notification to the functions concerned.


The responsibility for review and authority for the disposition of nonconforming products is defined in documented procedures. The review and disposition of Nonconforming products such as use as is, reject, repair, or rework is performed in accordance with documented procedures. Where required, any statutory/regulatory guidance shall be considered.

When required by contract, a product that does not conform to the customer’s specification will only be used or supplied with the customer’s prior knowledge and written consent. A description of the actual condition that has been accepted, with possible concessions or deviations, shall be recorded.

Any product that is repaired or reworked shall be re-inspected according to a Quality Plan and/or documented procedure.

**8.4 ANALYSIS OF DATA**

Statistical techniques are applied to gather and analyze the KPI data to demonstrate the effectiveness of the quality management system and evaluate steps toward the continual improvement of the system and helps gauge customer satisfaction. The results of the analysis will be discussed at the management review meetings.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 71 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

## 8.5 IMPROVEMENT

### 8.5.1 CONTINUAL IMPROVEMENT

As mentioned elsewhere, through the provisions and processes mentioned under Clause 4.1 of this document, augmented by the company/departmental procedures and work Instructions, the company ensures that the quality management system meets the quality objective and policy guidance.

In the quest for continually improving the quality of our products and achieving the goal of Customer Satisfaction, the company is committed to the summary implementation of the Quality Management System, including using the avenues of audit results, analysis of data, corrective & preventive actions, and continual customer communication.

The effectiveness of the quality management system will be discussed during the management review meetings.

The organization has established “Medical Product Complaint Handling” and “Product Recall” procedures that act as vehicles for the issuance of customer advisory notices when required.


Customer Complaint Reports generated per the Complaint Handling procedure shall be maintained. When the investigation reveals factors outside of the company that may have contributed to the complaint, such information will be shared with the customer and other relevant organizations.

The Customer Complaint Report (CCR) discusses the disposition of customer complaints and identifies the need for any failure analysis that may lead to corrective/preventive actions. The CCR also identifies the need for any reporting to the Regulatory authorities based on the Medical Product Complaint Handling procedure.

### 8.5.2 CORRECTIVE ACTION

Documented procedures are in place for implementing corrective and preventive action.

The company ensures that conditions adverse to quality such as customer complaints, returns, product nonconformities and supplier issues, including on the degree of magnitude and risk of the nonconformity, are identified and corrected.

 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhereyoulook™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 72 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

When processes are changed as the result of corrective actions, these changes shall be institutionalized, and appropriate procedures updated.

The company ensures customer complaints and reports of nonconformities are handled in a timely, effective manner.

The corrective action will include an investigation of the cause of the nonconformities relating to the product, process, and quality system, and recording the results of the investigation.

The investigation includes the corrective action necessary to prevent a recurrence.

Controls include follow-ups to ensure that the corrective actions are completed, effective, and do not have an adverse effect.

### 8.5.3 PREVENTIVE ACTION

Preventive action shall be taken as necessary pursuant to the


- Audit results.
- Assembly, Test, Inspection, and Process yield trends.
- Customer complaints/data.

These measures are analyzed to detect and eliminate potential causes of nonconformities.

The preventive action system includes the determination of steps needed to deal with any problem requiring preventive action. A preventive action system includes the initiation of preventive actions and checks to ensure that the preventive actions are effective and do not have an adverse effect.

Such action will be documented and discussed during the management review.



 <b>TELEDYNE</b> ANALYTICAL INSTRUMENTS Everywhere you look™	<h1>PRACTICES</h1>	<b>PRACTICE NUMBER</b> <b>CP100</b>
<b>COMPANY PRACTICES</b>	<b>TITLE:</b> <b>QUALITY MANUAL</b>	<b>PAGE: 73 OF 76</b>
		<b>REV: 25    REV DATE: 2023-02-14</b>
		<b>ECO #: 23-0006</b>

**ADDENDUM A**

**MEDICAL DEVICE REGULATORY COMPLIANCE**

**A.    PURPOSE**

This practice defines the company’s methods of complying with the United States Food and Drug Administration (Code of Federal Regulations 21CFR Part 820), European Medical Devices Directive, Canadian Medical Device Regulation, and other applicable statutory and regulatory requirements.

**B.    PRACTICE**

Documented procedures have been implemented to review, evaluate, and file all complaints; to determine if an investigation is necessary; to record the reason if no investigation is made; assign responsibility for deciding when not to investigate; and designate the personnel to perform these activities.

**ADDENDUM B**

**SARBANES-OXLEY 404 - INTERNAL CONTROLS**  
**COSO FRAMEWORK**

This document is under the control of the Plant Controller or designee and is not a part of the company’s Quality Management System, hence, not auditable under ISO 9001:2xxx, ISO 13485:2xxx, or other Company-adopted quality standards.

This document will form the guiding document for our internal financial controls and will be the framework for any Corporate Internal and External audits.

# PRACTICES

**COMPANY PRACTICES**

**TITLE:**

**QUALITY MANUAL**

**PAGE: 74 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

## ADDENDUM C

### CONTACT INFORMATION

This addendum lists various regulatory, registrar and notified bodies that are relevant to our business.

Standards, Directives, Regulations	Regulatory/Notified Body/Registrar Contact Information
ISO 9001:2xxx	<p><u>Registrar:</u> Intertek Testing Services 70 Codman Hill Road, Boxborough, MA 01719 T: 978-929-2100; F: 978-635-8595 <a href="mailto:Intertek-sc@intertek.com">Intertek-sc@intertek.com</a></p>
ISO 13485:2xxx and Canadian Medical Device Regulations	<p><u>Registrar:</u> BSI Management Systems, Inc., 12110 Sunset Hills, Ste. 200, Reston, VA 20190 T: 703-437-9000; F: 703-437-9001 <a href="mailto:Inquiry.msamericas@bsigroup.com">Inquiry.msamericas@bsigroup.com</a></p>
European Medical Devices Directive	<p><u>Notified Body:</u> BSI Product Services Kitemark House, Maryland Avenue Hemel Hempstead, HP2 4SQ, UK T: 011-44-1442 278 625; F: 011-44-1442 278 575 <a href="mailto:Product.Services@BSIGroup.com">Product.Services@BSIGroup.com</a></p> <p><u>Competent Authorities:</u> For a current list, refer to <a href="http://ec.europa.eu/enterprise/medical_devices/ca/list_ca.htm">http://ec.europa.eu/enterprise/medical_devices/ca/list_ca.htm</a></p> <p><u>Master Distributor:</u> Viamed Limited 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT, UK T: 011-44-1535 634542; F: 011-44-1535 635582 <a href="mailto:enquiries@viamed.co.uk">enquiries@viamed.co.uk</a></p>
US FDA QSR (21CFR820) 510(k) inquiries	<p>Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation (HFZ-401) 9200 Corporate Boulevard Rockville, MD 20850</p>



# PRACTICES

**COMPANY PRACTICES**

**TITLE:**  
**QUALITY MANUAL**

**PAGE: 75 OF 76**

**REV: 25 REV DATE: 2023-02-14**

**ECO #: 23-0006**

## ADDENDUM D

### OBLIGATION TO INFORM (THIS SECTION WILL BE UPDATED AS NEEDED)

Send/Report What?	To Whom?	By Whom?	By When?
ISO 9001:2xxx Certificate (Number 96-653x)	Customers and others, as needed	Sales and others, as requested (Either send a copy or refer to our web pages)	As required
ISO 13485:2xxx Certificate (Number FM 75659)	Customers and others, as needed	Sales and others, as requested (Either send a copy or refer to our web pages)	As required
Device Manufacturing License Renewal Form (License # 60335)	State of California, Dept of Public Health Food & Drug Branch	Quality Assurance	Before July 1 of the year the license expires
Medical Device – Adverse Event, Significant Change to Product, Process, or Quality System	Regulatory Bodies (FDA, MDD, HC, TGA, and others as applicable); EU Competent Authorities; Notified Bodies;	Quality Assurance (Refer to Adverse Event Notification guidelines on the web pages of various regulatory bodies in countries where we market our products too)	As indicated on CP207 – Medical Product Complaint Handling
Defects or failure to comply (Nuclear Containment Monitors and spare parts thereof)	The Regional NRC and the Utilities	Quality Assurance (Refer to CP205 and to the current version of 10CFR21 regarding reporting requirements)	As indicated on CP205.

