TABLE OF CONTENTS

1. GENERAL

1.1 Introduction / Purpose

This manual provides an overview of the Quality Management System (QMS) at Waters Corporation, Milford, Massachusetts, USA and the Global Distribution Center.

The quality system scope defined pertains to the Waters Milford site and the Franklin Global Distribution Center (GDC). The QMS is based on the requirements of ISO 9001, ISO 13485, In-Vitro Diagnostic Regulation (IVDR) 2017/746, In-Vitro Diagnostic Directive (IVDD) 98/79/EC, Canadian Medical Device Regulations SOR/98-282, and 21 CFR Part 820 in addition to meeting all applicable regulatory and customer requirements.

1.2 Applicable Milford Quality Management System Standards for Certification

ISO 9001:2015 Quality Management Systems - Requirements

ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for regulatory purposes

1.3 Milford Quality Management System Scope

Waters Milford has determined the quality management system scope appropriate to the Waters Milford site.

ISO 13485 is applicable to all products, processes and services in the medical device sector while ISO 9001 is applicable to all products, processes and services in other industry sectors. In determining the quality management system scope for ISO 9001 and ISO 13485, consideration was given to the context of organization, external & internal issues, relevant interested parties and their requirements, and products and services of the Waters Milford site.

For ISO 9001:2015, the Quality Management System scope is:

> The Design, Development, Manufacture, Management of Installation, Servicing, and Technical Support of High/Ultra Performance Liquid Chromatography (HPLC/UPLC) Instruments and Supplies, Associated Instrument Control Software, and Applications Software for General Research Use. The Manufacture, Installation, Servicing, and Technical Support of Mass Spectrometry (MS) Instruments and Supplies. The Design, Manufacture, and Servicing of Supercritical Fluid Chromatography (SFC) Instruments, their Components, Kits, and Spare Parts. The Manufacture of Spare Parts and Servicing for Supercritical Fluid Extraction (SFE) Instruments. The Management of Outsourced Manufacturing and Technical Support of Test Kits, Kit Reagents, Certified Reference Material, Calibrators, Controls, and Accessories for General Research Use. Receipt, Storage, and Distribution of Finished Goods at the Global Distribution Center.

For ISO 13485:2016, the Quality Management System scope is:

> The Design, Development, Manufacture, Installation, Servicing, and Technical Support of High/Ultra Performance Liquid Chromatography (HPLC/UPLC) Instruments and Supplies, and Associated Instrument Control Software.
> The Manufacture, Installation, Servicing, and Technical Support of In Vitro Diagnostic Mass Spectrometry (MS) Instruments and Supplies, and Applications Software.
> The Manufacture and Technical Support of In Vitro Diagnostic Test Kits, Reagents, Calibrators, Controls and Accessories.
> Receipt, Storage, and Distribution of Finished Goods.

1.4 Milford Quality Management System Non-Applicability of Requirements

Where any requirement of ISO 9001 or ISO 13485 is determined to be not applicable, Waters Milford will ensure that it does not affect Waters Milford ability or responsibility to ensure product conformity and enhance customer satisfaction.

ISO 9001:2015 Non-Applicability and Justification
None - All requirements are applicable.
ISO 13485:2016 Non-Applicability and Justification
7.5.5 Particular requirements for sterile medical devices Clause 7.5.5 is not applicable as Waters Milford products are not subject to sterilization. **7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems** Clause 7.5.7 is not applicable as Waters Milford products are not subject to sterilization and so not require sterile barrier systems. **7.5.9.2 Particular requirements for implantable medical devices** Clause 7.5.9.2 is not applicable as Waters Milford products are not implantable medical devices. **8.2.6 Monitoring and Measurement of Product** The monitoring and measurement requirement for implantable medical devices is not applicable as Waters Milford products are not implantable medical devices.

1.5 Quality Policy

The Quality Policy, document 730000639, supports the Corporate strategic vision, provides a framework for setting quality objectives, and establishes our commitment to meet requirements/regulations. It also identifies our commitment to continually improve our products, processes and customer satisfaction. The Quality Policy is communicated, understood, and applied throughout Waters Milford through the Learning Management System, Town Halls, and site management reviews. As appropriate, it is made available on the Corporate Waters website to all relevant interested parties.

1.6 Definitions & Abbreviations

Not Applicable

1.7 Roles & Responsibilities

Roles	Responsibilities
Waters Management	It is the responsibility of management to ensure implementation of this Quality Manual.
Milford Management	Site representatives that support the Quality Management System: Complaint Handling, Design Quality, Engineering, Manufacturing, Quality, Research & Development, Supplier Quality, Supply Chain, Purchasing, etc.

1.8 References & Related Documents

Refer to Appendix II

2. COMPANY INFORMATION

Waters Corporation, headquartered in Milford, Massachusetts: develops, manufactures, services, and markets instruments, software, accessories, and supplies for analytical and preparative liquid chromatography Ultra Performance Liquid Chromatography (UPLC), High Performance Liquid Chromatography (HPLC), Supercritical Fluid Chromatography (SFC), and Mass Spectrometry (MS) Systems. Waters Corporation manages the Outsourced Manufacturing of Test Kits, Kit Reagents, Certified Reference Material, Calibrators, Controls, and Accessories. Waters' markets include In-Vitro Diagnostic medical device and non-medical device industries. In addition, Waters Corporation has maintained a commitment to leading edge programs in the area of distribution, service, support, customer education, and compliance. The Executive Committee (EC) comprises the Chief Executive Officer and a team of senior leaders accountable for each for the Global Functions that business is structured into as defined below.

Global Function	Responsibilities
Waters Division	Design and development of Instruments (LC and MS), consumables and Informatics products, Sales and Marketing.
Global Operations	Manufacture and distribution of Instruments (LC and MS), consumables and Informatics products. Quality oversight and support. Outsourced Manufacture and distribution of Test Kits, Kit Reagents, Certified Reference Material, Calibrators, Controls, and Accessories.
TA Instruments	Design, development, manufacture, distribution and ongoing support of thermal analysis and rheology products.
Clinical Business Unit	Design, development, and ongoing support of IVD products, inclusive of Instrument (LC and MS), consumables and Informatics products plus assays for clinical diagnostics and forensics. Sales and Marketing of IVD products. Quality and Regulatory Affairs oversight and support.
Finance/IT	Accounting and business financial support. Provision and maintenance of IT infrastructure
Human Resources	Personnel related process oversight and support.
Legal	Legal oversight and support.
Strategy & Transformation	Development and execution of business strategy.
Communications	Corporate level internal/external communication content and platforms.

Customers

Our customers work from the early stages of discovery and development through final quality control and assurance. Our major market segments are: Pharmaceutical, biotechnology, semiconductor, chemical, environmental testing, food and beverage companies, university laboratories, government and private analytical

and research laboratories, defense and regulatory agencies, clinical laboratories, hospitals, medical schools, and medical research institutes.

Research and Development

Waters' Milford, product development includes the design of new liquid chromatography instruments, software for instrument control, applications, and accessories.

Since these instruments are characterized by a rapid rate of technological change. Waters makes significant investments in research, development and product improvements to meet/exceed customers' needs/expectations.

Manufacturing

Waters' manufacturing activities are conducted at the facilities in Milford. For some products, Waters uses contract manufacturer organizations (CMO) and original equipment manufacturers (OEM). Manufacturing activities include the production of parts and assemblies used in its products. Some of the parts are built by outside qualified suppliers. Products incorporate mechanical, electronic, chemical, and optical components. Prior to shipment to the customer: completed instruments and component products are tested and evaluated to meet specified requirements.

The following is a breakdown of IVD products and Waters Milford operational responsibilities:

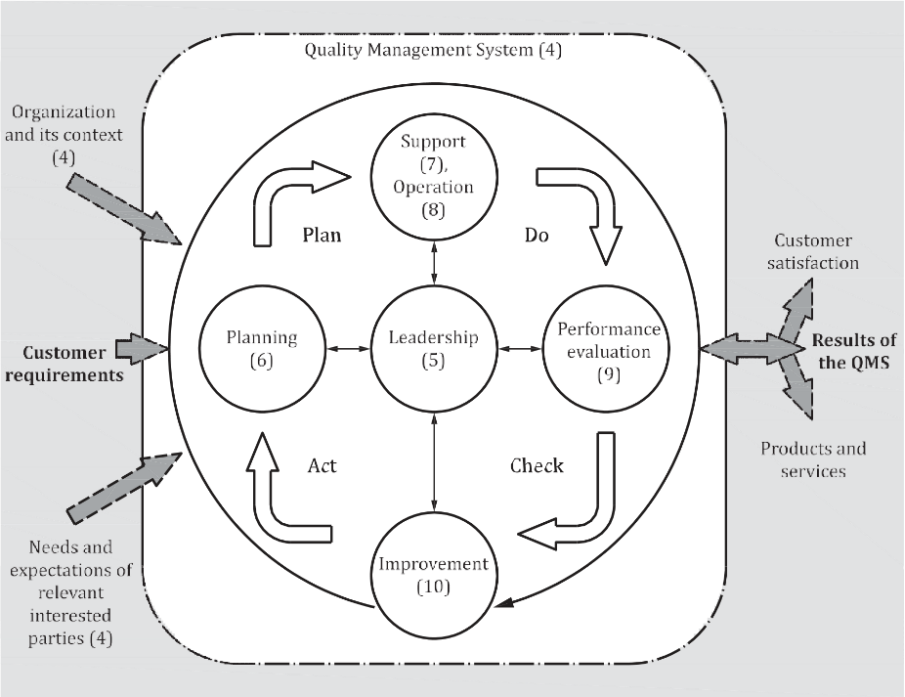
Product Family	Waters Milford Operational Responsibilities
Reagent Kits	Complaint Handling & Reporting, Outsourced Manufacture
Chemistry Consumables	Design & Development, Complaint Handling & Reporting
Mass Spectrometers	Manufacturing, Installation, Servicing and Complaint Handling & Reporting
Liquid Chromatography	Design & Development, Manufacturing, Installation, Servicing, Complaint Handling & Reporting
Software	Design & Development, Manufacturing, Installation, Servicing, Complaint Handling & Reporting

3. MILFORD QUALITY MANAGEMENT SYSTEM OVERVIEW

3.1 Process Approach

The QMS is based on the PDCA (Plan-Do-Check-Act) cycle, as depicted below:

- **PLAN**: Plan the processes, resources, goals, objectives, etc. to meet requirements and achieve intended outcomes.
- **DO**: Implement processes according to planned requirements.
- **CHECK**: Evaluate, Monitor, Measure processes and their results.
- **ACT**: Determine and implement improvements.



Extract from Figure 2: ISO 9001: 2015 - Representation of the structure of this International Standard in the PDCA cycle

3.2 Milford Quality Management System Processes

The QMS addresses all applicable requirements referenced in Section 1.1. Waters Milford uses a risk-based approach to determine the extent of the QMS documentation to achieve compliance and intended outcomes.

QMS processes are determined and implemented. The QMS process requirements will be defined in the specific policy and/or procedure which will be supported as applicable by additional process documentation.

Waters Milford Business Operations Process Map (Appendix I) provides a high-level overview of the interaction of essential Operation/Product Realization processes, Management processes, and Support processes, including alignment with planning and risk activities across all processes. Appendix II provides references to the QMS process, policies, and procedures.

4. CONTEXT OF WATERS MILFORD ORGANIZATION

Waters Milford Management evaluates and determines the organizational context of Waters Milford site, interested parties and their requirements, internal and external issues that are relevant to our business purpose, strategy, and QMS. The output from context of organization evaluation provides Waters Milford Management with an understanding of key factors that influence the business and QMS. The information is used as an input in determining quality management system processes, objectives, improvements, risk mitigations, etc. Waters Milford Management monitors and reviews information regarding interested parties and their requirements, and internal and external issues that are relevant. The context of organization information is subject to change as business and factors affecting our business and quality management system changes. This information is reviewed, at least annually, as part of the site management review process.

5. LEADERSHIP

5.1 Leadership Commitment

Waters Senior Management demonstrates leadership and commitment to the Quality Management System. This is accomplished by:

- Being accountable for the QMS effectiveness.
- Maintaining & improving customer satisfaction.
- Establishing a quality policy and quality objectives compatible with the organization context and strategy.
- Ensuring the integration of the QMS into relevant business processes.
- Promoting the use of the process approach, risk-based thinking, and improvement.
- Providing the needed QMS resources.
- Communicating the importance of conformance with QMS requirements and effective quality management.
- Engaging, directing, and supporting people, as applicable to contribute to the effectiveness of the QMS.
- Supporting relevant management to demonstrate leadership in their area.
- Being customer focused ensuring customer and applicable statutory requirements are determined, understood, and met.
- Assessing risks/opportunities affecting conformity and customer satisfaction are addressed.
- Ensuring that responsibilities and authorities for relevant roles are assigned, defined, documented communicated, and understood:
    - Including the interrelation of personnel managing, performing, and verifying work affecting quality
    - Including appropriate independence and authority
- Ensuring that planned changes are controlled and do not adversely affect the QMS integrity.
- Assigning a Management Representative with specific responsibility and authority for oversight of the QMS.

5.2 Management Representative

Management has appointed the Regional Quality Director as the Management Representative. The Management Representative is a member of the Milford site. Has the responsibility and authority for the oversight of the QMS including:

- Ensuring the quality management system processes are documented.
- Reporting to Executive Management on the performance/effectiveness of the QMS and the need for any improvements.
- Ensuring the promotion of awareness of applicable regulatory and QMS requirements.

6. PLANNING

Milford Management manages the risks and opportunities relevant to the business, QMS, product, and service. This includes consideration of internal and external issues, the needs and expectations of interested parties, as well as business and quality management system processes. When actions are determined necessary to address risks / opportunities: They are planned and implemented to ensure the QMS achieves intended results. Additionally, Waters Milford verifies the effectiveness of any actions taken.

Quality Objectives are established at relevant functions, levels, and processes, as needed. Waters Milford Management ensures that appropriate planning is determined and implemented to achieve the specific objectives.

When changes are required to the QMS, Quality ensures that the changes are implemented in a planned manner ensuring that the change does not adversely affect the integrity of the QMS.

7. SUPPORT

7.1 Resources

Milford Management determines and provides appropriate resources to establish, implement, maintain, and improve the QMS. This improvement includes the operation and control of processes. In determining the required resources, consideration is given to the capabilities of, and constraints on, existing internal resources. This includes what can be obtained from external providers. Resources include provision of people, infrastructure, work environment, monitoring & measurement, and organizational knowledge. These resources are needed for the operation and control of processes in order to achieve conformity of products and services.

7.2 Competence, Awareness & Communication

Milford Management:

- Determines the competency of personnel performing work for Milford that affects the performance and effectiveness of the QMS and ensures that personnel are competent.
- Ensures that personnel performing work that affects the performance and effectiveness of the QMS are aware of the Quality Policy, relevant Quality Objectives and applicable QMS information.
- Establishes internal and external communications processes to ensure that appropriate communication takes place regarding the QMS; including its effectiveness.

7.3 Documented Information

Milford Management ensures that QMS documentation is established, implemented, and maintained using a risk-based approach for QMS effectiveness. This will ensure conformity to applicable standards and regulations. The Milford QMS documentation as outlined in Appendix III is controlled and consists of:

- Policy - provides an interpretation of a regulation or standard via guiding principles and defines minimum core requirements with the intentions and direction of an organization as formally expressed by its top management.
- Procedure - defines the process from input to output and describes “what happens” within the organization resulting in products (services) and shows how we will fulfil the policy.
- Work Instruction - defines the execution to the requirements and describes who, what, how and when to execute a specific task.
- Form – a document to be completed to record data / results, to show that polices, procedure and work instructions have been followed.
- Template - a document that contains guidelines for the type of information required for each section, which is specific for each document family. Standard information is included. A template is a pre-formatted document that serves as a starting point for a new document.
- Records - documented information containing results achieved or demonstrating objective evidence of activities performed, events occurred, or statements made.

Data Integrity includes the following:

- Review by authorized personnel for suitability and adequacy
- Controlled distribution, access, retrieval and use
- Available and suitable for use, where and when it is needed
- Adequately protected, stored and preserved
- Control of change process
- Retention and disposal control
- Records retained shall be protected from unintended alterations

- Protecting any confidential health information to support any regulatory requirements
- ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate)

8. OPERATION

8.1 Operational Planning & Control

Waters Milford plans, implements, and controls processes to meet product and service conformity requirements, including any actions to address risks or opportunities. The planning and control includes:

- Determining requirements and quality objectives for the products and services.
- Determining and establishing criteria for processes and the acceptance of products/services.
- Required verification, validation, monitoring, measurement, inspection & test, handling, storage, distribution, and traceability activities specific to the product as applicable.
- Determining and providing required resources.
- Implementing applicable controls for the processes.
- Determining, establishing, and maintaining required documentation to provide evidence of process conformity and the resulting product/service meets requirements.
- Determining products and services to be obtained from external providers and ensuring that outsourced processes are controlled.
- Controlling planned changes and reviewing the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.
- Determining and establishing a process for risk management for product realization and maintaining records of risk management.

8.2 Requirements for Products & Services

Waters Milford's primary focus is to be an active partner with our customers, understanding their environment and identifying solutions suitable to their needs and applications, which will both meet, and exceed, their expectations. Customer communication also includes but is not limited to:

- Providing information relating to products and services
- Handling enquiries, contracts or orders, including changes
- Obtaining customer feedback and complaints, advisory notices, recalls
- Handling or controlling customer property
- Establishing specific requirements for contingency actions, when applicable
- Product and/or service requirements including changes are determined and reviewed prior to acceptance

8.3 Design & Development

Waters Milford plans and controls product design and development activities to ensure requirements are met. Design and Development projects are scaled based on the requirements and product complexity. Each design and development project includes planning, determining inputs, generating design outputs, applying appropriate design and development controls including review, verification, validation, transfer, change control, risk management activities, creation, and maintenance of design history files.

8.4 Control of Externally Provided Products, Processes and Services

Waters Milford defines, reviews, and communicates purchasing requirements to suppliers and ensures that externally provided products, processes, and services conform to requirements. Waters Milford is responsible for external provider conformity by determining controls to be applied and identifying/managing external provider risks. Waters Milford evaluates, approves, and re-evaluates suppliers to defined criteria and monitors their performance. Waters Milford determines and implements appropriate verification of externally provided products/processes/ services and addresses any supplier issues proportionate to the risk associated with the purchased product/service in compliance with applicable regulatory requirements.

8.5 Production & Service Provision

Waters Milford production and service processes are planned, documented, carried out, monitored and controlled to ensure product conforms to specification. Controlled production and service provision includes, but is not limited to:

- Standard Operating Procedures/Instructions/Plans/Specifications/Drawings - defining production methods, process/product characteristics, and acceptance criteria
- Qualification and use of suitable Infrastructure and Environment
- Measurement and monitoring of process parameters and product characteristics at appropriate stages
- Availability and use of suitable monitoring and measurement equipment
- Provision of competent personnel
- Implementation of defined operations for labeling and packaging
- Implementation of any required cleaning, installation, and service activities
- Implementation of appropriate product preservation
- Implementation of any required validation and re-validation activities for processes, equipment, & software
- Implementation of any applicable actions to prevent human error
- Implementation of product release, delivery and post-delivery activities
- Maintaining appropriate identification and traceability
- Managing any customer property
- Establishing and retaining verified and approved records providing appropriate traceability
- Control of production process and document changes

8.6 Production & Service Release

Waters Milford conducts monitoring and measurements at appropriate stages to ensure that product and service requirements have been met. Products or services are not released until planned arrangements have been completed or released under an authorized concession by relevant authority and/or customer where resulting product/service is accepted.

8.7 Control of Nonconforming Outputs

Waters Milford controls nonconforming product to prevent its unintended use or delivery including nonconformances detected after delivery and takes appropriate action based on the risk.

9. PERFORMANCE EVALUATION

9.1 Monitoring, Measurement, Analysis and Evaluation

Waters Milford determines and implements suitable methods for monitoring, measuring, analysis and evaluation to assess the performance and effectiveness of the QMS. Waters Milford ensures timely complaint handling and, as applicable, regulatory reporting in accordance with applicable regulatory requirements.

Customer satisfaction is evaluated to monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.

Data Analysis of the QMS process output will provide information regarding the processes, process performance results and their effectiveness.

9.2 Internal Audit

Waters Milford conducts internal audits at planned intervals to determine if the quality management system conforms to requirements referenced in Section 1.1. The Internal Audit process determines whether it is effectively implemented and maintained. Internal audit results are reported to applicable Management. Based on audit findings, correction or corrective action is determined and implemented.

9.3 Management Review

Milford Management reviews the performance of quality system periodically to assess the effectiveness, alignment with strategic direction, adequacy, and continuing suitability of the quality management system to identify any improvements needed. Relevant QMS input information/data will be reviewed/discussed and relevant output decisions will be documented relating to improvement opportunities, changes including new or revised regulatory requirements, resources, and risks.

10. REGULATORY COMPLIANCE

Article 10 of the IVDR regulation lists the aspects to be addressed by the QMS which includes a Strategy for Regulatory Compliance. The following list summarizes Waters' Regulatory Strategy for IVD's manufactured and the procedures and plans in place that govern each section:

- Person Responsible for Regulatory Compliance, 730007636: Corporate Policy for EU Authorization Rep, UK Responsible Person, and Persons Responsible for Regulatory Compliance
- Communication with Competent Authority and Notified Body:
  - WAT000502SO: Procedure for Regulatory Submission and Change Assessment of Medical Devices
  - 730001138: Post Market Surveillance Planning and Reporting
- Managing Relationships with Economic Operators, 730008051: IVDR Importer and Distributor Procedure
- UDI and Labelling Compliance,
  - 730000504: Finished Product Labelling Requirements,
  - 730002994: Unique Device Identification (UDI) Policy
- Vigilance & Post Market Surveillance Compliance:
  - 730001138: Post Market Surveillance Planning and Reporting
  - 730007943: Post Market Surveillance Policy
  - WAT000504SO: Reportable Events and Incidents
  - WAT000506SO: Corporate Procedure - Product Recall
- Conformity Assessment Compliance, 730007916: IVD Technical Documentation Procedure

11. IMPROVEMENT

Waters Milford will maintain and ensure the continued suitability, adequacy, and effectiveness of the QMS. Waters Milford determines opportunities for improvement and selects applicable improvement actions for implementation. Actions may include product/service/process/QMS improvements including corrections, changes, corrective actions, preventive actions, continual improvements, etc. Corrective actions or Preventive actions required to eliminate the cause/potential cause of nonconformities will be determined and implemented using a risk-based approach proportionate to the effects of the nonconformities or potential nonconformities.

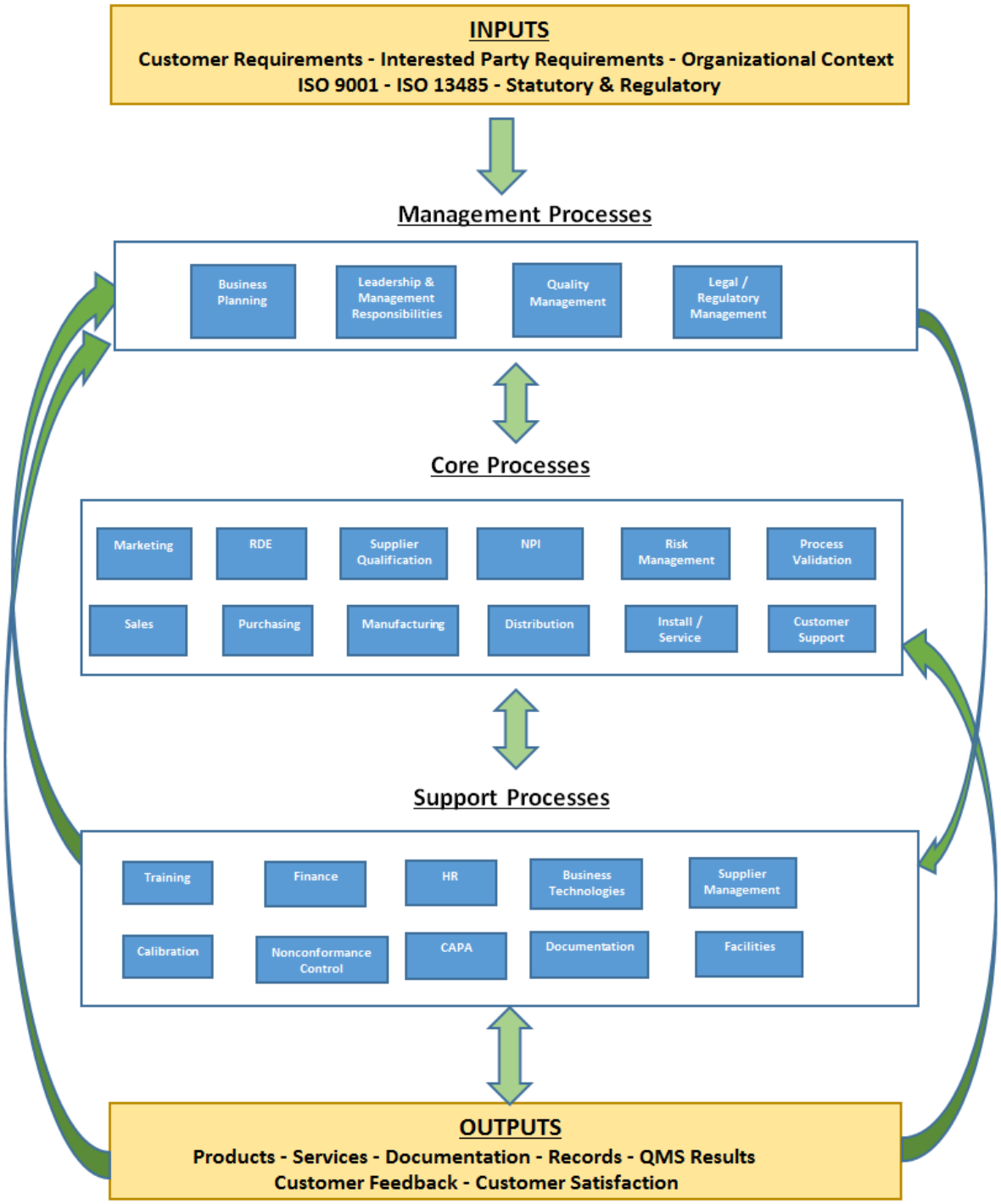
12. APPENDICES / ATTACHMENTS

Appendix I: Waters Milford QMS Processes & Interactions

Appendix II: Quality Documentation System Cross Reference

Appendix III: Quality Management System Document Hierarchy

Appendix I: Waters Milford QMS Processes & Interactions



Appendix II: Quality Documentation System Cross Reference

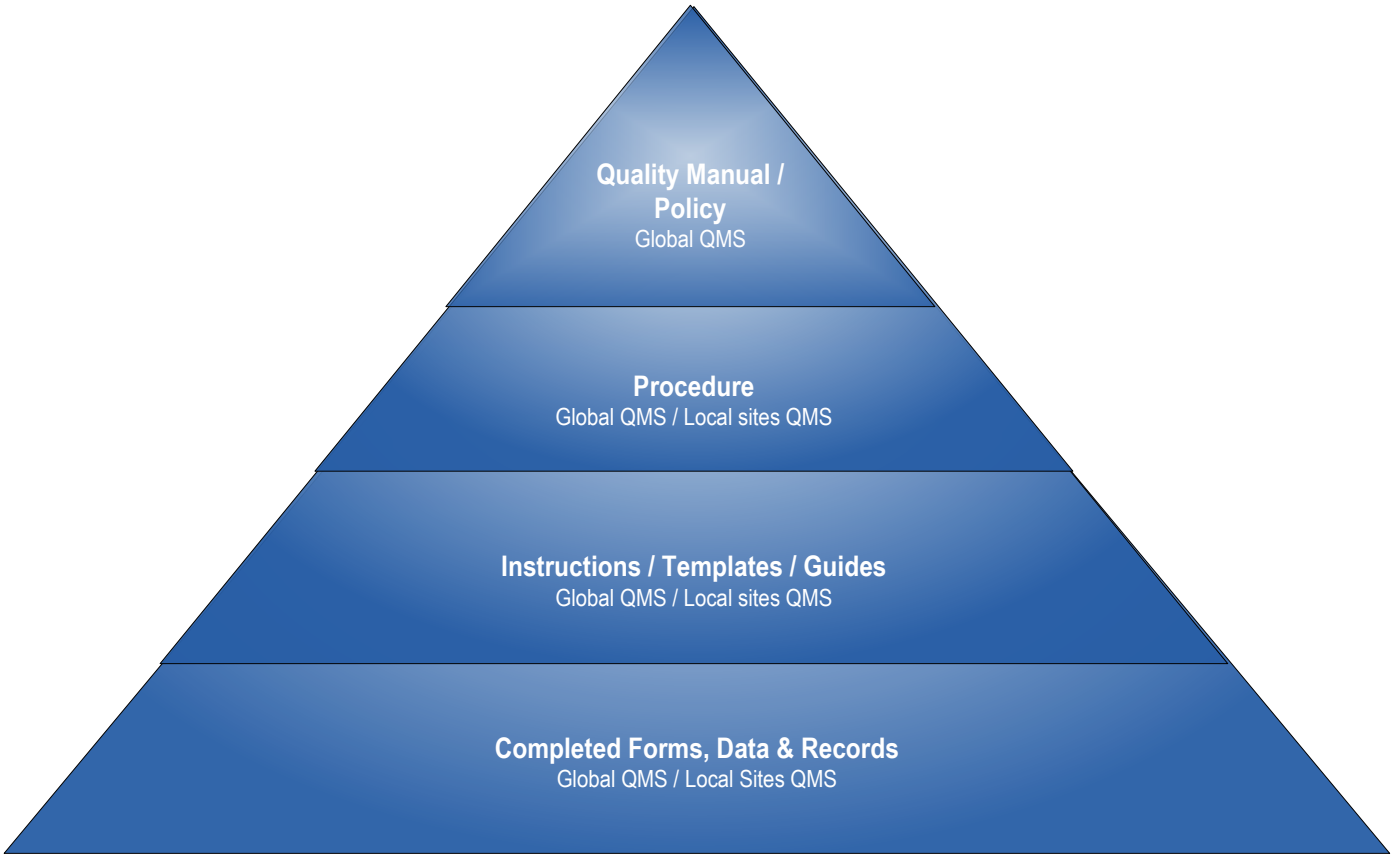
ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	IVDR	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
4 Context of the Organization	4 Quality Management System	21CFR820.5	Annex IX QMS Article 10 General Obligations of Manufacturers	Management Core	WAT000001QM Waters Business Operations Quality Manual 730001504 Outsourced Process List 730001930 Management Review (MR)
4.4 Quality Management System and its Processes 7.5 Documented Information	4.2 Documentation Requirements	21CFR820.20e, 40 21CFR820.180, 181, 184, 186 21 CFR Part 11	Annex II Technical Documentation Annex IX QMS	Management Core Support	WAT000001QM Waters Business Operations Quality Manual 730002900 Global Document Management Policy 730006393 Global Control of Documented Information WAT000050MP Waters Record Retention Global Policy 730002947 Global Quality Record Retention Schedule
5 Leadership 5.1 Leadership and Commitment 5.2 Policy	5 Management Responsibility 5.3 Quality Policy	21CFR820.20a	Annex IX QMS	Management Core Support	730000639 Waters Quality Policy WAT000103MP Executive Management Review Procedure 730001930 Management Review (MR) 730000945 Global Training Policy
6 Planning	5.4 Planning	21CFR820.20 a,d		Management Core Support	WAT000004MP Production Planning 730007116 Global Quality Planning Process 730000945 Global Training Policy
5.3 Organization Roles, Responsibilities and Authorities	5.5 Responsibility, Authority and Communication	21CFR820.20b1,b3	Annex 17 EU Declaration of Conformity Annex 18 CE Marking of Conformity Annex IX QMS	Management Core Support	WAT000001QM Waters Business Operations Quality Manual 730007116 Global Quality Planning Process 730000945 Global Training Policy
9.3 Management Review	5.6 Management Review	21CFR820.20c		Management Core Support	WAT000103MP Executive Management Review Procedure 730001930 Management Review (MR) 730000945 Global Training Policy
7 Support 7.2 Competence	6 Resource Management	21CFR820.25, 70		Management Core Support	WAT000001QM Waters Business Operations Quality Manual 730000945 Global Training Policy
7 Support	6.3 Infrastructure 6.4 Work Environment & Contamination Control	21CFR820.70 a, c-h, 21CFR820.75, 21CFR820.170		Management Core Support	545 Business Information Systems Recovery Standard 730001503 Facilities Preventive Maintenance Procedure

ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	IVDR	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
8 Operation 8.3 Design and Development of Products and Services 8.3.5 – 8.3.6	7 Product Realization 7.1 Planning of Product Realization 7.2 Customer Related Processes 7.3 Design and Development 7.3.3 – 7.3.10	21CFR820.20d, 21CFR820.30a-j 820.70b	Annex I: Safety and Performance Requirements Article 10 Risk Management Annex II: Technical Documentation	Management Core Support	730000370MP Global Policy – Risk Management 730000945 Global Training Policy 730001236 Market Requirements Document Procedure 730001798 Waters Software Development Process 730001095 Global Design Control Policy 730000985 Waters Product Development Process 730002180 Global Services Product Development Procedure 730000995 WPDP Design Verification Procedure 730000997 WPDP Design Validation Procedure 730006236 Global Engineering Change Policy WAT077822SO Engineering Change Procedure 730000991 WPDP Design History File Index Procedure 730001138 Post Market Surveillance Planning & Reporting 730001681 Design/Technical Documentation File Procedure 730007916 IVD Technical Documentation Procedure
8.4 Control of Externally Provided Processes, Products and Services	7.4 Purchasing	21CFR820.50a, b	Chapter II Article 10-14 Obligations of Economic Operators	Management Core Support	WAT077817SO Managing the Qualified Suppliers List 730010316 Global Audit Management Procedure 730002112 Global Supplier Quality Agreement Procedure WAT077814SO Supplier Score Card (SSC) WAT077940SO Incoming Inspection Procedure 730000945 Global Training Policy 730008051 IVDR Importer and Distributor Procedure
8.4 Control of Externally Provided Processes, Products and Services	7.5 Product and Service Provision 7.5.6 Validation of Processes	21CFR820.70a, c-h, 21CFR820.75, 21CFR820.170, 21CFR820.200	Annex I: Safety and Performance Requirements	Management Core Support	WAT000340MP GSS Service Support Process WAT000342MP Global Service New Product Support Procedure 730000945 Global Training Policy 730001835 Process Validation Procedure 730000617 CSV: Global Software Tool Validation Policy
8.5.2 Identification and Traceability	7.5.8 Identification 7.5.9 Traceability	21CFR820.60, 21CFR820.65 21CFR820.80e	Annex II Technical Documentation Article 10 General Obligations of Manufacturers Article 18 CE Marking of Conformity	Management Core Support	WAT000020MP Data Products Serial Number Procedure WAT079006MP Instrument Serial Number Procedure 730000504 Finished Product Labeling Requirements 730000945 Global Training Policy 730002994 Unique Device Identification (UDI) Policy
8.5.3 Property Belonging to Customers or External Providers	7.5.10 Customer Property	None		Management Core Support	WAT077911SO Milford Customer Repair Process 730000945 Global Training Policy

ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	IVDR	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
8.5.4 Preservation	7.5.11 Preservation of Product	21CFR820.120 21CFR820.130, 21CFR820.140, 21CFR820.150, 21CFR820.160	Article 24 Unique Device Identification System Annex VI Unique Device Identifier (UDI-DI) Annex I Chapter III Requirements Regarding Information Supplied with the Device	Management Core Support	WAT000046MP Milford Stockroom Procedure 730003902 Packaging 730003893 GDC Receiving Procedure 730002994 Unique Device Identification (UDI) Policy
8.5 Production and Service Provision	7.6 Control of Monitoring and Measuring Equipment	21CFR820.72		Management Core Support	730001799 Operating Procedure, Calibration and Preventive Maintenance
8.5 Production and Service Provision	8 Measurement, Analysis and Improvement	21CFR820.250		Management Core Support	730000859 Global Data Analysis Policy
7.1.5 Monitoring and Measuring Resources	8.2 Monitoring and Measurement 8.2.1 Feedback 8.2.2 Complaint Handling	21CFR820.198	Article 78 – 85 Post-Market Surveillance System of Manufacturer Annex XIII Post Market Performance Follow-up Annex III Post Market Surveillance Plan Chapter VI Clinical Evidence, Performance Evaluation and Performance Studies	Management Core Support	730001385 Global Escalation Procedure WAT000103MP Executive Management Review Procedure 730001930 Management Review (MR) 730000394MP Global Policy – Complaint Handling 730000680 Device Master Record WAT000504SO Reportable Events and Incidents 730001138 Post Market Surveillance Planning and Reporting 730007943 Post Market Surveillance Policy
	8.2.3 Reporting to Regulatory Authorities		Article 15 Person Responsible for Regulatory Compliance Article 11-12 Authorized Representative and Change of Authorized Representative Article 31 – 46 Notified Bodies Article 10 General Obligations of Manufacturers		730007636 Corporate Policy for EU Authorized Representative, UK Responsible Person, and Persons Responsible for Regulatory Compliance, and CH-Rep WAT000502SO Procedure for Regulatory Submission and Change Assessment of Medical Devices WAT000506SO Corporate Procedure - Product Recall 730000492 Market Withdrawal Procedure
9.2 Internal Audit	8.2.4 Internal Audit	21CFR820.22	Annex IX QMS	Management Core Support	730010316 Global Audit Management Procedure
8.6 Release of Products and Services	8.2.5 Monitoring and Measurement of Processes	21CFR820.22, 21CFR820.250		Management Core Support	730000859 Global Data Analysis Policy

ISO 9001:2015	ISO 13485:2016	Quality System Regulation - 21CFR Part 820	IVDR	Primary Management / Core / Support Processes (to align with App. I)	Document # & Description
8.5.1 Control of Production and Service Provision	8.2.6 Monitoring and Measurement of Product	21CFR820.80b-e, 21CFR820.250 21CFR820.86		Management Core Support	WAT078433SO Receiving Incoming Material WAT000235MP System Readiness Group Management Procedure
8.7 Control of Nonconforming Outputs	8.3 Control of Nonconforming Product	21CFR820.90a,b		Management Core Support	730000970 Global Nonconformance Policy 730001028 Nonconforming Product Process – Milford WAT000074MP Stop Ship Procedure 730000634 Global Product Improvement Procedure
9.1.3 Analysis and Evaluation	8.4 Analysis of Data	21 CFR 820.250	Article 83 Trend Reporting (Post Market)	Management Core Support	730000859 Global Data Analysis Policy
10 Improvement 10.2 Nonconformity and Corrective Action 10.3 Continual Improvement	8.5 Improvement 8.5.2 Corrective Action 8.5.3 Preventive Action	21CFR820.20c, 21CFR820.100, 21CFR820.198	Article 10 General Obligations of Manufacturers	Management Core Support	730001930 Management Review (MR) WAT000103MP Executive Management Review Procedure 730000394MP Global Policy – Complaint Handling 730000548 Global CAPA Process

Appendix III: Quality Management System Document Hierarchy



DOCUMENT HISTORY

(Note: Complete Document History may be obtained via the Document Management System.)

VERSION:	38	**ORIGINATOR:**	RoseMarie Stamboulides	**Change ID:**	N/A
Description of Change: APPENDIX II – Removed references to WAT078440SO, 730002126, 730000622. Added reference to global Audit process (730010316).					
VERSION:	37	**ORIGINATOR:**	RoseMarie Stamboulides	**Change ID:**	N/A
Description of Change: Section 1.1 – Included IVDD 98/79/EC and Canadian Medical Device Regulations SOR/98-282. Sections 3.2, 9.2 – Revised to include reference to requirements identified in Section 1.1. Section 10 – Included 730001138, 730002994, WAT000506SO; updated document titles as needed. APPENDIX II – Updated document descriptions, as needed.					
VERSION:	36	**ORIGINATOR:**	RoseMarie Stamboulides	**Change ID:**	N/A
Description of Change: Section 1.3 – Modified scope of ISO 9001 and ISO 13485 to align with current scope of certificates. Section 2 – add distribution to company information and Global Operations. Section 5.2 – Amended title. APPENDIX II – Removed obsolete documents; updated document descriptions, as needed. Updated to current version of global template.					
VERSION:	35	**ORIGINATOR:**	RoseMarie Stamboulides	**Change ID:**	N/A
DESCRIPTION OF CHANGE: **APPENDIX II – REMOVED OBSOLETE DOCUMENTS; REVISED SEC. 2**					
VERSION:	34	**ORIGINATOR:**	George Abouzeid	**Change ID:**	N/A
DESCRIPTION OF CHANGE: UPDATED THE QUALITY MANUAL THROUGHOUT TO INCLUDE THE IVDR REQUIREMENTS. **APPENDIX II – REMOVED OBSOLETE DOCUMENTS; ADDED GLOBAL DOCUMENTS, AS APPLICABLE**					
VERSION:	33	**ORIGINATOR:**	RoseMarie Stamboulides	**Change ID:**	N/A
DESCRIPTION OF CHANGE: UPDATED TO QUALITY MANUAL TEMPLATE. **GENERAL – REMOVED REFERENCE TO CANADIAN MEDICAL DEVICE REGULATIONS** **SEC. 1.3 – UPDATED SCOPE SECTIONS FOR ISO 9001 & ISO 13485 TO ALIGN WITH ACTIVITIES** **SEC. 1.5 – REMOVED LANGUAGE AND ADDED REFERENCE DOCUMENT NUMBER** **SEC. 2 – ADDED SFC** **APPENDIX II – REMOVED OBSOLETE DOCUMENTS; ADDED GLOBAL DOCUMENTS, AS APPLICABLE**					