TIDEPOOL Document	Title: IMDRF SaMD N23, ISO 13485, US FDA QMS Map		
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Purpose

This reference document maps the requirements of the IMDRF SaMD Working Group's Final Document N23, *Software as a Medical Device (SaMD): Application of Quality Management System*, to the requirements of ISO 13485:2016, *Medical devices - Quality management systems - Requirements for regulatory purposes*, to the QMS/compliance requirements of US FDA cited below.

References

- IMDRF SaMD WG/N23 FINAL: 2015, http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf
- ISO 13485:2016, Medical devices - Quality management systems - Requirements for regulatory purposes
- 21 CFR 820, Quality System Regulations
- 21 CFR 801, Labeling
- 21 CFR 803, Medical Device Reporting
- 21 CFR 806, Reports of Corrections and Removals
- 21 CFR 807, Establishment Registration and Device Listing (includes 510(k) and PMA requirements)
- 21 CFR 7, Enforcement Policy (recall authority)
- 21 CFR 830, UDI

Note: EU MDR quality system references are not included in this version. Those requirements and procedures will be added as part of Tidepool's EU MDR project.

Responsibility

Regulatory/Quality are responsible for creating and maintaining this QMS matrix.

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
5.0--SaMD QUALITY MANAGEMENT PRINCIPLES	Quality management strategy	4 Quality Management System 4.1 General Requirements 4.2 Documentation Requirements	820.5 Quality System	DOC-0003 Tidepool Quality Manual Section 4, Quality Management System DOC-9001 Tidepool Quality System Index	
	Management responsibility	5.0 Management Responsibility	820.20 Management Responsibility	SOP-0020 Management Review	
6.0--SaMD LEADERSHIP AND ORGANIZATIONAL SUPPORT					
6.1--LEADERSHIP AND ACCOUNTABILITY IN THE ORGANIZATION	Management Responsibility	5.0 Management Responsibility	820.20(b) Organization	DOC-0003, section 5, Management Responsibility	
	Management Commitment	4.1 Management Responsibility			
	Customer focus	5.2 Customer Focus	820.20(a) Quality Policy	DOC-0003, section 5.9.3 , Quality Policy	
	Quality Policy	5.3 Quality Policy			
	Quality Planning	5.4 Quality Planning	820.20(d) Quality Planning	DOC-0003, section 5.11	
	Responsibility and Authority	5.5 Responsibility, Authority & Communication	820.20(b)(1) Responsibility & Authority	DOC-0003, section 5.4, 5.5, Management Responsibility	
	Management Representative	5.5.2 Management Representative	820.20(b)(3) Management Representative	DOC-0003, section 5.12	
	Internal Communication	5.5.3 Internal Communication		DOC-0003, section 5.6, Management Responsibility TRN-0005 Quality System Communication	
	Management Review	5.6 Management Review	820.20(c) Management Review	DOC-0003, Section 6 SOP-0020 Management Review	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
	Internal Audit	8.2.4 Internal Quality Audits	820.22 Quality Audit	DOC-0003, section 10.5, Internal audits SOP-0021 Internal Quality Audit	
6.2--RESOURCE AND INFRASTRUCTURE MANAGEMENT	Resource Management	6 Resource Management	820.25 Personnel	DOC-0003, section 7, Resource Management SOP-0003 Employee Qualifications and Training	
6.2.1--PEOPLE	Provision of Resources	6.1 provision of resources 5.1e Management Commitment	820.20(b)(2) Resources	DOC-0003, section 7.1, Resource Management DOC-0003, Section 7.1, 7.2.3	
	Skill Management	6.1 Provision of Resources 6.2 Human Resources	820.25(a) General	DOC-0003, section 7 SOP-0003 Employee Qualification & Training; TRN-0100 Tidepool Training Matrix Also: TRN-0002 Employee Security Practices TRN-0003 Tidepool HIPAA Privacy and Confidentiality Training TRN-0004 Tidepool HIPAA Policy Overview	
6.2.2--INFRASTRUCTURE AND WORK ENVIRONMENT	Infrastructure	6.3 Infrastructure 7.5.1 Control of Production and Service Provision 7.5.6 Validation of Production and Service Provision	820.70(f) Buildings, 820.70(g) Equipment	DOC-0003, section 8.1, 8.2, Infrastructure and Work Environment DOC-0003,, section 9.15.4 (control of production & service, validation of processes) SOP-0034 Validation of Software Tools and Services	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
	Work environment	6.4 Work Environment and Contamination Control	820.70(c) Environmental Control	DOC-0003, section 8.3, Infrastructure and Work Environment DOC-0003,, section 9.15.4 (Preservation of product)	
7.0--MANAGING SaMD LIFECYCLE SUPPORT PROCESSES					
7.1--PRODUCT PLANNING	Quality Planning	5.4 Planning	820.20(d) Quality Planning	DOC-0003, section 5.11	
	Planning of product realization	7.1 Planning of Product Realization	820.30(a) General (Design Controls), 820.70(a) Production and Process Controls	DOC-0003, section 9, Product Realization SOP-0005 Design, Development and Release	
	Design planning	7.3.1 General (Design & Development) 7.3.2 Design & Development Planning	820.30(a) General, 820.30(b) Design and Development Planning	SOP-0005 Design, Development and Release sections 6.1, 7.1	
7.2--RISK MANAGEMENT: A PATIENT SAFETY FOCUSED PROCESS	Planning of product realization	7.1 Planning of Product Realization	820.30(g) Design Validation	DOC-0003, section 9.8 SOP-0005 Design, Development and Release, section 12 SOP-0006 Risk Management SOP-0009 Cybersecurity Risk Assessment	
7.3--DOCUMENT CONTROL AND RECORDS	Quality System records	4.2 Documentation Requirements 7.1 Planning of Product Realization	820.186 Quality System Records	DOC-0003 DHR: section 9.12 DMR/MDF: section 4.10 SOP-0005 Design, Development and Release, DHF, sections 7.6, 15 SOP-0006 Risk Management	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
				SOP-0009 Cybersecurity Risk Assessment	
	Documentation Requirements – General	4.2.1 General (Documentation Requirements)	820.20(e) Quality System Procedures	DOC-0003, section 4.9; DOC-9001 Tidepool Quality System Index SOP-0001, sections 4, 5	
	Quality Manual	4.2.2 Quality Manual		DOC-0003 Tidepool Quality Manual	
	Document Control	4.2.4 Control of Documents 4.2 Documentation Requirements.	820.40 Document Controls	DOC-0003, sections 4.9, 4.10 SOP-0001 Control of Documents 2020-01-17 Tidepool FDA Electronic Signature Certification	
	Control of Records	4.2.5 Control of Records 4.2 Documentation Requirements.	820.180 Records	DOC-0003, sections 4.9, 4.10, 4.11 SOP-0002 Control of Quality Records	
	Device Master Records (DMR)	4.2.3 Medical Device File	820.181 Device Master Record	DOC-0003, DMR/MDF: section 4.10	
7.4--CONFIGURATION MANAGEMENT AND CONTROL	Document Control	4.2.4 Control of Documents 4.2 Documentation Requirements.	820.40 Document Controls	SOP-0001 SOP-0005 section 7.3 (for SW product configuration management)	
	Control of Records	4.2.5 Control of Records 4.2 Documentation Requirements.	820.180 Records	SOP-0002 Control of Quality Records SOPs include a Documentation section that states how and where	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
				applicable documents and records are controlled	
	Control of design and development changes	7.3.9 Control of Design and Development Changes 7.3.8 Design & Development Transfer 7.3.7 Design & Development Validation	820.30(i) Design Changes	DOC-0003, section 9.10; SOP-0005, section 14 (design changes) SOP-0005, section 13 (design transfer) SOP-0005, section 12 (design validation) SOP-0026 Regulatory Reporting	
	Production and service provision – General Requirements	7.5.1 Control of Production and Service Provision	820.70(a) Production and Process Controls, 820.70(g) Equipment, 820.70(h) Manufacturing Material, 820.70(i) Automated Processes	DOC-0003, section 9.15 (process controls, automated processes, IMTE) Manufacturing material N/A)	
	Identification	7.5.8 Identification 7.5.3 Installation Activities	820.60 Identification	DOC-0003, section 9.15.4	
	Traceability	7.5.9 Traceability	820.65 Traceability	DOC-0003, section 9.15.4	
	Status Identification	7.5.8 Identification 7.5.3 Installation Activities	820.86 Acceptance Status	DOC-0003, section 9.15.5	
7.5--MEASUREMENT, ANALYSIS AND IMPROVEMENT OF PROCESSES, ACTIVITIES AND PRODUCT	Measurement, analysis, and requirement	8 Measurement, Analysis & improvement		DOC-0003, section 10	
	Conformity assurance	8.1 General	820.80 Receiving, in-process- and finished device acceptance	DOC-0003, 9.15.5	
	Feedback/Complaints	7.2.3 Communication 8.2.1 Feedback 8.2.2 Complaints Handling	820.198 Complaint Files, 810 Mandatory Device Recalls,	SOP-0007 Complaint Handling SOP-0010 User Experience Assessment	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
		8.2.3 Reporting to Regulatory Authorities	806 Corrections and Removals, 7 Voluntary Recalls	SOP-0011 Partner Complaint Sharing SOP-0013 Conducting a Recall SOP-0012 Field Safety Corrective Actions SOP-0026, Regulatory Reporting SOP-0024 Customer Feedback	
	Internal Audits	8.2.4 Internal Quality Audits	820.22 Quality Audit	DOC-0003, section 10.5 SOP-0021 Internal Quality Audit	
	Process monitoring	8.2.5 Monitoring and measurement of process	820.70(a) Production and Process Controls	DOC-0003, section 9.13 - 9.15 SOP-0004 Corrective and Preventive Action SOP-0020 Management Review	
	Product monitoring	8.2.6 Monitoring and measurement of product	820.80(a) Receiving, In-process, and Finished Device Acceptance – General	DOC-0003, sections 9.15, 10.6 SOP-0020 Management Review,	
	Nonconforming product	8.3 Control of Nonconforming Product	820.90(a) Non-Conforming Product	DOC-0003, section 10.8; SOP-0036 Handling Nonconformances	
	Data analysis	8.4 Analysis of Data		DOC-0003, section 10.7; SOP-0020 Management Review SOP-0035, Analysis of Data	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
				TMP-0010 Management Review Meeting Template	
	Improvement	8.5 Improvement		DOC-0003, section 10	
	Improvement- general	8.5.1	803 Medical Device Reporting	DOC-0003, section 10.4.3 (complaints); SOP-0008 Reportable Events	
	Corrective action	8.5.2 Corrective Action	820.100 Corrective and Preventative Action	DOC-0003, section 10.6, 10.7, 10.8 SOP-0004 Corrective & Preventive Action	
	Prevention action	8.5.3 Preventive Action			
	Customer communication	7.2.3 Communication	820.198 Complaint Files	SOP-0007, Complaint Handling; SOP-0011 Partner Complaint Sharing SOP-0024 Customer Feedback SOP-0030 Customer Communications	
	Control of design and development changes	7.3.9 Control of Design and development Changes	820.70b Product and Process Changes, 820.30(i) Design Changes	DOC-0003, section 4.2, 5.11, 6.2, 6.4, 9.8 SOP-0005, section 14;	
	Production and service provisions - General requirements	7.5.1 Control of production and service provision 7.3.10 Design and Development Files	820.184 Design History File	SOP-0005, section 15 (DHF/DDF)	
7.6--MANAGING OUTSOURCED PROCESSES, ACTIVITIES AND PRODUCTS	Purchasing process	7.4.1 Purchasing Process	820.50 Purchasing Controls	SOP-0023 Purchasing Process	
	Vendor evaluation	7.4.1	820.50(a) Evaluation of Suppliers, Contractors, and Consultants	SOP-0022 Vendor Management	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
	Purchasing information	7.4.2 Purchasing Information	820.50(b) Purchasing Data	SOP-0023 Purchasing Process	
	Verification of purchased product	7.4.3 Verification of *purchased product*	820.80 Receiving, in-process, and finished device acceptance	DOC-0003, section 9.15 SOP-0023, section 4.5 SOP-0034 Validation of Software Tools and Services	
	Improvement - general	8.5.1 General (Improvement)	803 Post Market Surveillance	DOC-0003, section, section 10.10 SOP-0027 Postmarket Surveillance	
8.0--SaMD REALIZATION AND USE PROCESSES					
8.1--REQUIREMENTS MANAGEMENT	Customer requirements capture	7.2.1 Determination of requirements related to product (Customer-related process)	820.30(c) Design Input	DOC-0003, section 9.2 (customer requirements), 9.5 SOP-0005, section 8 (sources of design inputs)	
	Contract review	7.2.2 Review of requirements related to products		SOP-0030, Customer Communications, section 5.1	
	Customer communication	7.2.3 Communication		SOP-0030 Customer Communications	
	Quality System record	4.2 Documentation Requirements 7.1 Planning of Product Realization	820.186 Quality System Record	DOC-0003, section 4.11 SOP-0002, Control of Quality Records SOP-0005, section 5.3 (backups). Also, each design control activity includes documentation requirements	
	Documentation Requirements - General	4.2.1 General (Document Requirements)	820.20(e) Quality System Procedures	DOC-0003, section 4.9 SOP-0001 Control of Documents	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
				SOP-0002 Control of Quality Records	
	Quality Manual	4.2.2 Quality Manual		DOC-0003	
	Doc Control	4.2.4 Control of Documents	820.40 Document Controls	DOC-0003, section 4.9 SOP-0001 Control of Documents SOP-0005, sections 6.1, 7.1 (Jira project management & tickets)	
	Control of Records	4.2.5 Control of Records 4.2 Documentation Requirements.	820.180 Records	DOC-0003, section 4.9 SOP-0001, Control of Documents SOP-0002 Control of Quality Records	
	Requirements Records	7.1d Planning of Product Realization	820.80 Receiving, In-process, and Finished Device Acceptance	DOC-0003, section 9.13 (purchasing controls), 9.14 (purchasing information), 9.15 (verification of purchased product) SOP-0023, section 4.5 SOP-0034 Validation of Software Tools and Services	
8.2--DESIGN + 8.3-- DEVELOPMENT	Design & Development (D&D)	7.1 Planning of Product Realization 7.3.2 Design and Development Planning	820.30(b) Design and Development Planning	DOC-0003, section 9.4 SOP-0005, sections 6.1, 7.1 SOP-0006, Risk Management SOP-0009, Cybersecurity Risk Management	
	Design inputs	7.2.1 Customer Related Processes 7.2.2 Review of Requirements Related to	820.30(c) Design Input	DOC-0003, section 9.2 (customer requirements), 9.5 SOP-0005, section 8	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
		Product 7.3.3 Design and Development Inputs		(design inputs)	
	D&D Outputs (including DHF)	7.3.4 Design and Development Outputs 7.3.10 Design and Development Files	820.30(d) Design Output, 820.30(j) Design History File	DOC-0003, section 9.6 SOP-0005, section 9 (design outputs) SOP-0005, section 15 (DHF/DDF)	
	Design review	7.3.5 Design and Development Review	820.30(e) Design Review	DOC-0003, section 9.9 SOP-0005 section 10	
	Design Transfer	7.3.8 Design and Development Transfer	820.30(h) Design Transfer	DOC-0003, section 9.11 SOP-0005, section 13	
	Control of D&D changes	7.3.9 Control of Design and Development Changes	820.30(i) Design Changes	DOC-0003, section 9.10 SOP-0005, section 14	
8.4--VERIFICATION AND VALIDATION	Design verification	7.3.6 Design and Development Verification	820.30(f) Design Verification	DOC-0003, section 9.7 SOP-0005, section 11 SOP-0006, section 5.3.1 (throughout product realization), 12.3 (risk control verification)	
	Design validation	7.3.7 Design and Development Validation	820.30(g) Design Validation	DOC-0003, section 9.8 SOP-0005, section 12	
	Verification of purchased product	7.4.3 Verification of Purchased Product	820.80(b) Receiving Acceptance	DOC-0003, section 9.15 SOP-0023, section 4.5	
8.5—DEPLOYMENT	Customer Communication	7.2.3 Communication (Customer related process)		DOC-0003, section 9.3 SOP-0030 Customer Communication SOP-0005, section 13.4.4, 13.4.5 (release notes, app store)	
	Production & service provision	7.5 Production and Service provision		DOC-0003, section 9.15.4	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
				SOP-0005, sections 13.1 - 13.3 (transfer to production, product approval, deployment) SOP-0028 Labeling Control	
	Contamination Control	6.4.2 Contamination Control	820.70(e) Contamination Control	DOC-0003, section 8.3 SEC-0012 Information Security Policy SEC-0005, Access Control SEC-0006, Operations Security Policy	
	Installation	4.2.3 Medical Device File 7.5.3 Installation Activities 7.5.8 Identification 7.5.11 Preservation of Product	820.170 Installation	DOC-0003, section 4.10 (DMR, MDF); section 9.15.4 (installation, identification, preservation) SEC-0005, Access Control SEC-0006, Operations Security Policy	
	Distribution	4.2.3 Medical Device File 7.1 Planning of Product Realization 7.5.8 Identification 7.5.11 Preservation of Product	820.160 Distribution	DOC-0003, section 4.10 (DMR, MDF); 9.1 (planning); 9.15.4 (identification, preservation of product, distribution) SEC-0005, Access Control SEC-0006, Operations Security Policy SOP-0005, section 13.3	
	Servicing	4.2.3 Medical Device File 7.1 Planning of product Realization 7.5.4 Servicing Activities 7.5.8 Identification	820.200 Servicing	N/A, see DOC-0003, section 1.7	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
8.6--MAINTENANCE	Customer Communication	7.2.3		SOP-0030, Customer Communication SOP-0026, Regulatory Reporting SOP-0005, section 14 (design changes); section 7.3 (versioning w/respect to changes); section 13.4.4, 13.4.5 (release notes, app store)	
	Production & Service provision		820.30, Design Changes	DOC-0003, section 9.10 SOP-0005, section 14	
	Servicing	7.5.1.2.3	820.200	N/A, see DOC-0003 section 1.7	
	Customer property (Confidential health information; partner-supplied components, software, etc)	7.5.4		DOC-0003, section 9.15.4 (Customer Property) SEC-0004, Data Management Policy TRN-0002 Employee Security Practices TRN-0003 Tidepool HIPAA Privacy and Confidentiality Training TRN-0004 Tidepool HIPAA Policy Overview	
	Monitoring & measuring Devices	7.6	820.72	DOC-0003, section 9.15.4	
	Feedback/Complaints	7.2.3 Communication, 8.2.1 Feedback, 8.2.2 Complaints Handling, 8.2.3 Reporting to Regulatory Authorities	820.198 Complaint Files, 822 Post-Market Surveillance, 810 Mandatory Device Recalls,	DOC-0003, sections 9.3 (customer communication), SOP-0007 Complaint Handling SOP-0011, Partner Complaint Sharing	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
			806 Corrections and Removals, 7 Voluntary Recalls	SOP-0012, Field Safety Corrective Actions SOP-0013, Conducting a Recall SOP-0024 Customer Feedback SOP-0026 Regulatory Reporting SOP-0027 Postmarket Surveillance SOP-0030 Customer Communication	
8.7-- DECOMMISSIONING	Control of records	4.2.5 Control of Records 4.2 Documentation Requirements.	820.180 Records, 820.186	SOP-0002 Control of Quality Records SOP-0005, section 5.3 (backup & recovery), section	
	Documentation Requirements - General	4.2.1 General (Documentation Requirements)	820.20(e) Quality System Procedures	DOC-0003 section 4.9 SOP-0001 Control of Documents	
	Quality Manual	4.2.2 Quality Manual		DOC-0003 Quality Manual	
	Document Control	4.2.4 Control of Documents	820.40 Document Controls	DOC-0003 section 4.9 SOP-0001 Control of Documents	
	Production and service provision – General requirements	7.5.1 Control of production and service provisions 4.2.3 Medical Device File	820.181 Device Master Record	DOC-0003, section 4.10 (DMR, MDF)	
	Product realization	7 Product Realization	820.140 Handling 820.150 Storage 820.160 Distribution 820.180 Records 820.184 Device History Records	DOC-0003, section 9.15.4 (DHR; Installation, Distribution; Preservation of product) SOP-0002, Control of Records	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
			820.186 Quality System Records 820.200 Servicing	SOP-0005 (Handling, Storage):, section 7.3 (versioning); 7.5.2 (github repositories & tags); 13 (released version) Servicing N/A; See DOC-0003 section 1.7 (Servicing is N/A)	
ADDITIONAL CLAUSES NOT INCLUDED DIRECTLY IN N23					
	Process Validation	7.5.6 Validation of process for production and service provision	820.75 Process Validation	DOC-0003, section 9.15.4	
	Traceability Documents	7.5.9 Traceability	820.65 Traceability	DOC-0003, 9.15.4	
	Status Identification	7.5.8 Identification	820.60 Identification	DOC-0003, 9.15.4	
	Device Packaging	4.2.3 Medical Device File 7.5.8 Identification 7.5.11 Preservation of Product	820.130 Device Packaging	N/A, see DOC-0003 section 1.7	
	Handling	4.2.3 Medical Device File 7.1 Planning of Product Realization 7.5.8 Identification 7.5.11 Preservation of Product	820.140 Handling	DOC-0003, section 4.10 (MDF); 9.1 (planning); 9.15.4 (identification, preservation) SOP-0005, “unique URL” references throughout; (github repositories & tags); section 13.1 (transfer to production); section 13.3 (deployment to production)	
	Storage	4.2.3 Medical Device File 7.1 Planning of Product Realization 7.5.8 Identification 7.5.11 Preservation of Product	820.150 Storage	DOC-0003, section 4.10 (MDF); 9.15.4 (software repositories, identification, preservation) SOP-0005, section 7.5, (github repositories & tags); 13.1 (transfer to	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
				production), 13.3 (deployment to production)	
	Monitoring & Measurement	8.2 Monitoring and Measurement		DOC-0003, section 10	
	Production Personnel	6.2 Human Resources	820.70(d) Personnel	DOC-0003, section 7.2 (Competency)	
	Production and provision – General requirements	7.5.1e Control of production and service provision 4.2.3 Medical Device File 7.5.8 Identification 7.5.11 Preservation of Product	820.120 Device Labeling	DOC-0003, section 9.15.4 (labeling, identification, preservation)); section 4.10 (MDF) SOP-0028 Labeling Control	
	Issue of implementation of Advisory notices	7.2.3 Communication 8.2.1 Feedback 8.2.2 Complaints Handling 8.2.3 Reporting to Regulatory Authorities	806 Corrections and Removals	SOP-0007 Complaint Handling SOP-0012, Field Safety Corrective Actions SOP-0013, Conducting a Recall SOP-0024 Customer Feedback SOP-0026 Regulatory Reporting	
	Medical Device Tracking	MDR clauses	822 Medical Device Tracking Requirements	N/A to Tidepool's products	
	Device Classification	MDR clauses	860 Medical Device Classification Procedures	DOC-0003, section 5.1 (meeting regulatory requirements) SOP-0033 Marketing Authorization	
	Labelling & UDI	MDR clauses	801 Labeling (801.20) Label to bear a unique device identifier:	DOC-0003, section 9.15.4 (Labeling/Instructions for use; Identification & Traceability)	

IMDRF N23 (QMS) Topic		ISO 13485:2016 Clauses	US FDA 21 CFR	Tidepool SOPs/DOC	Comments
				SOP-0028 Control of Labeling, section 5.7	