SaMD Documentation Map

START HERE

Business Case + Product Concept/ Mktg Spec/ Target Product Profile

Pre-Development Research

Product Development Plan

Software Development Plan (SDP)

Risk Mgmt Plan (RMP)

Hazards & Harms List

System Hazard Analysis (SHA)

Usability Risk Analysis (URA)

HF/Usability Formative Reports

R&D Reports

Security Risk Management Plan

Threat Model

Cybersecurity Risk Analysis (CRA)

User Requirements (URS)

Software Test Plan

Software Requirements (SRS)

Software Architectural Design (SWAD)

Cybersecurity Architectural Views (CAV)

Software Detailed Design (SDD)

SBOM

Vulnerability Scan of SBOM

Labeling Requirements

Security Requirements

Security Testing

security testing service

3rd party pentest report

Security Test Plan

Security Risk Management Report

Software Deployment/ Operational Instructions

Cybersecurity Post-Market Management Plan

User Manual (IFU)

E-labeling

IFU

SW Unit Verif

SW Unit Verif Summary:
- Unit Testing
- Code Reviews
- Static/Dynamic Analysis

Test Method Validations

Software Test Tool Validations

Design Review

Design Review Records

Defect Tracking

SW System Verif

SW System Verification Protocols

Software Trace Matrix

SW V&V Report (SVVR)

SW Release Record (SRR)

SW Unresolved Anomalies Report

System Validation

URA

Usability Summative Protocol

Clinical Valid Protocol

SHA

IRB

CRO

Usability Summative Report

Clinical Valid Report

HFE Report

URS

Risk Mgmt Review

Risk Mgmt Report

RMP

SHA

URA

Risk Mgmt File

SDP

SRS

SWAD

SDP

SVVR

SRR

SDD

CRA

SBOM

CAV

510(k) Submission (eSTAR)

Device Description, Indications for Use, Predicate, etc.

Performance Testing - Bench

Performance Testing - Clinical

Software
- Documentation Level Evaluation
- Software Description
- Risk Management File
- SW Requirements Specification (SRS)
- System and SW Architecture Design
- SW Development, Config Mgmt, and Maintenance
- SW Testing as Part of V&V
- SW Version History
- Unresolved SW Anomalies
- SW Design Specification (SDS)

Cybersecurity
- Risk Management Report
- Threat Model
- Cybersecurity Risk Assessment
- Software Bill of Materials (SBOM)
- Assessment of Unresolved Anomalies
- Cybersecurity Testing
- Architecture Views
- Cybersecurity Metrics
- Cybersecurity Controls
- Cybersecurity Labeling
- Cybersecurity Management Plan

Proposed Labeling

Legend
- Document dependency
- Testing to requirements
- XXX Document abbreviation
- Service providers
- Activities
- Risk
- Software
- Cybersecurity
- Human Factors
- Labeling

Before starting V&V testing:
- -Design requirements are released
- -SW design documents are released
- -Software Test Candidate Released (design freeze)
- -Test protocols are released
- -Test methods are validated
- -Test tools, including SW test scripts, are calibrated
- -Personnel are trained

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Aaron Joseph: Navigating Medical Device Documentation
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