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)

Security Risk Management Plan

Cybersecurity Risk Analysis (CRA)

Threat Model

HF/Usability Formative Reports

R&D Reports

User Requirements (URS)

Software Requirements (SRS)

Software Architectural Design* (SWAD)

Software Detailed Design (SDD)

SBOM

Labeling Requirements

Security Requirements

Software Deployment/ Operational Instructions

*SWAD includes security architecture

System Validation

Software Trace Matrix

SW Release Record (SRR)

SW System Verif

SW System Verification Protocols

SW V&V Report (SVVR)

Defect Tracking

SW Unresolved Anomalies Report

SW Unit Verif

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

Test Method Validations

Software Test Tool Validations

Design Review

Design Review Records

security testing

3rd party pentest report

Security Testing

Security Test Plan

Security Risk Management Report

Software Security & Maintenance Plan

User Manual (IFU)

E-labeling

IFU

URA

Usability Summative Protocol

Clinical Valid Protocol

SHA

IRB

CRO

Usability Summative Report

Clinical Valid Report

HFE Report

Risk Mgmt Review

Risk Mgmt Report

Risk Mgmt File

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
- -Software Test Candidate Released (design freeze)
- -Test protocols are released
- -Test tools are calibrated
- -Test methods are validated
- -Test equipment is validated (including SW test scripts)

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