Software Validation Documentation Checklist

Planning & Classification

- Software Development Plan with lifecycle activities
- Intended use and functionality clearly defined
- Safety classification (FDA Level of Concern or IEC 62304 A/B/C)
- List of applicable standards and regulatory scope

Requirements & Design

- User Needs and Software Requirements Specification (SRS)
- Software Architecture or Design Description (SDS)
- Interface and module-level specifications
- Requirements Traceability Matrix (RTM)

Implementation & Verification

- Documented coding standards and version control
- Verification Plan and detailed test protocols
- Unit, integration, and system testing reports
- Test results mapped to requirements

Risk & Validation

- Risk analysis per ISO 14971 with control measures
- Cybersecurity assessment (if applicable)
- Validation Plan and real-use validation summary
- Defect tracking and resolution logs

Release & Maintenance

- Final software release documentation
- Installation and deployment instructions
- Maintenance procedures and update plan
- Problem reporting and post-market monitoring plan