

Medical Device Software Quality Assurance Checklist

Project Information

Project Name	
Device/Software Name	
Version	
Date	

Quality Assurance Checklist

Item	Description	Yes	No
Requirements Specification	Is there a documented and reviewed software requirements specification (SRS)?		
Risk Management	Have software risks been identified, assessed, and documented?		
Design Documentation	Are software architectures and detailed designs documented and approved?		
Traceability	Is there bidirectional traceability between requirements, risks, tests, and design?		
Code Review	Were code reviews conducted and documented according to procedure?		
Unit Testing	Have all units/modules been tested and test results documented?		
Integration Testing	Has integration testing been performed and results documented?		
System Testing	Has system-level testing been conducted to verify software meets requirements?		
Change Management	Are software changes controlled, reviewed, and documented?		
User Documentation	Is user documentation prepared and reviewed?		
Verification & Validation	Has V&V plan been executed and results documented?		
Release Approval	Is there documented approval for software release?		

Comments/Notes

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Review and Approval

Name	Title	Date	Signature