

IEC 62304: Medical device software – Software life cycle processes

7 Software Risk Management

8 Software Configuration Management

5.1 SW
Development
Planning

5.1 SW
Requirements
Analysis

5.1 SW
Architectural
Design

5.1 SW
Detailed
Design

5.1 SW Unit
Implement. &
Verification

5.1 SW
System
Testing

5.1 SW
Release

9 Software Problem Resolution

Medical Device Software Software Life Cycle Processes

Michael Brown



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