

# VectorCAST for FDA and IEC 62304

## Software Safety Certification for Medical Devices and Equipment

A wide variety of medical devices incorporate embedded software. Some of these such as: X-ray scanners, heart rate, blood pressure and breathing monitors, are used for analyzing patients. Others such as defibrillator and medication pumps, are used to treat patients.

In both cases, people's health and safety depend on the medical software deployed being reliable, safe and bug-free.

Medical devices sold in the United States must be approved by the U.S. Food and Drug Administration (FDA). The FDA has a formal process for device manufactures to follow for certification including guidelines for software validation.

### What is IEC 62304

The International Electrotechnical Commission created the IEC 62304 standard. The standard, formulated to govern the requirements for medical software, describes the process that medical software must go through in order to be approved for use in Europe. The standard includes guidelines for testing any software components that are part of a medical device.

### Tool Qualification

IEC 62304 recommends that software tools such as testing tools be qualified in order to provide evidence of software tool suitability for use when developing a safety-related item or element such that confidence can be achieved in the correct execution of activities and tasks required by IEC 62304. Such qualification must indicate that an erroneous result from the tool could lead to the violation of any safety requirement and that efforts were made to prevent or detect such errors.

Vector Software provides an off-the-shelf tool qualification package that demonstrates that the VectorCAST tool output is accurate within embedded development environments.

### Key Features

- > Supports all levels of code coverage required by IEC 62304
  - Statement
  - Branch
  - MCDC
- > Automatic generation and compilation of complete test stubs and driver programs
- > Automatic regression testing
- > IEC 62304 compliant test report generation
- > Test execution host, simulator, and embedded target system
- > Automatic test case template creation to achieve 100% code coverage
- > Full support for software unit and integration testing

### What is VectorCAST for FDA and IEC 62304

The VectorCAST embedded software test platform supports the creation and management of test cases to prove that the low level software requirements have been tested and is also useful for a variety of robustness testing activities such as range and out of bounds testing. Additionally, the VectorCAST tools support the capture and reporting of structural code coverage at all levels recommended by IEC 62304.

### Proving Due Diligence for FDA Audits

VectorCAST tools are successfully used by clients demonstrating due diligence with FDA software quality requirements. Whether your device is Class I, II or III, the VectorCAST tools provide a dependable and repeatable testing process for your medical device software development.

### VectorCAST Tool Qualification Deliverable Process

VectorCAST provides intended use validation in the form of qualification documents. The qualification documents consist of Tool Operational Requirements (TOR) and Tool Qualification Data (TQD). TOR describes requirements for

VectorCAST tools and TQD, the associated tests and test results. Coverage and test case reports are exportable to regular HTML or text for easy integration into product documentation.

**VectorCAST for FDA and IEC 62304 Qualification Kit**

**Includes:**

**Tool Operational Requirements (TOR)**

> The VectorCAST functionality in verifiable requirements

- > Project operational environment (compiler, platform, target, etc.)
- > Configuration management process
- > Method for attaining verification that VectorCAST has been satisfactorily tested against specified requirements

**Tool Qualification Data (TQD)**

- > Tool qualification test data and results
- > Test scripts for re-execution

Software Documentation	Class A	Class B	Class C
<b>Software development plan</b>	Must contain contents to sections 5.1 IEC 62304:2006. The plan's content list increases as the class increases, but a plan is required for all classes.		
<b>Software requirements specification</b>	Software requirements specification conforming to 5.2 IEC 62304:2006. The content list for the software requirements specification increases as the class increases, but a document is required for all classes.		
<b>Software architecture</b>	Not required.	Software architecture to 5.3 IEC 62304:2006. Refined to software unit level for Class C.	
<b>Software detailed design</b>	Not required.		Document detailed design for software units. (5.4).
<b>Software unit implementation</b>	All units are implemented, documented and source controlled (5.5.1).		
<b>Software unit verification</b>	Not required.	Define process, tests and acceptance criteria (5.5.2, 5.5.3). Carry out verification (5.5.5)	Define additional tests and acceptance criteria (5.5.2, 5.5.3, 5.5.4). Carry out verification (5.5.5).
<b>Software integration and integration testing</b>	Not required.	Integration testing to 5.6 IEC 62304:2006.	
<b>Software system testing</b>	Not required.	System testing to 5.7 IEC 62304:2006.	
<b>Software release</b>	Document the version of the software product that is being released (5.8.4).	List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.	

VectorCAST products are used during these phases to automate ISO 26262 required testing

**More information:** [www.vector.com/vectorcast](http://www.vector.com/vectorcast)