

The IEC 62304:2015 Medical device software – software life cycle processes governs how software in safety classes A to C is developed and verified.

Section 5.1.4 “Software development standards, methods and tools planning” and Annex C.7 (referencing IEC 61508) define tool qualification criteria for Class C software.

CANTATA

CANTATA HYBRID
Certification Engine for Google Tests

QAMISRA

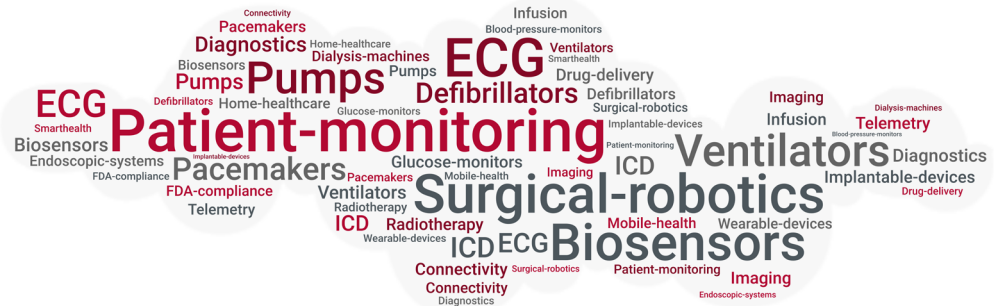


Cantata (including Cantata Hybrid) and QA-MISRA have been certified by SGS-TÜV Saar GmbH against IEC 61508 Part 3 Section 7.4.4 as class T2 offline support tools suitable for the verification of medical devices software up to IEC 62304 Class C.

Tool Certification kits for each are available free of charge.

Medical Device applications

QA Systems software verification tools are used across all medical device domains.



Hamilton Intelligent Ventilation

“An out-of-the-box solution would not be possible. We were therefore very impressed when we were informed that a custom part of Cantata could be provided, specifically for this environment. There existed a very professional approach to meeting our particular needs.”

Research and Development Director,
Hamilton Medical

“Our engineer took to Cantata really quickly, and acceptance was not an issue... since then it’s been straightforward to maintain the unit tests and create new ones... The tool is now an integral part of our development process”

Software Development Director,
Creo Medical



CROMA Generator & Surgical Instruments



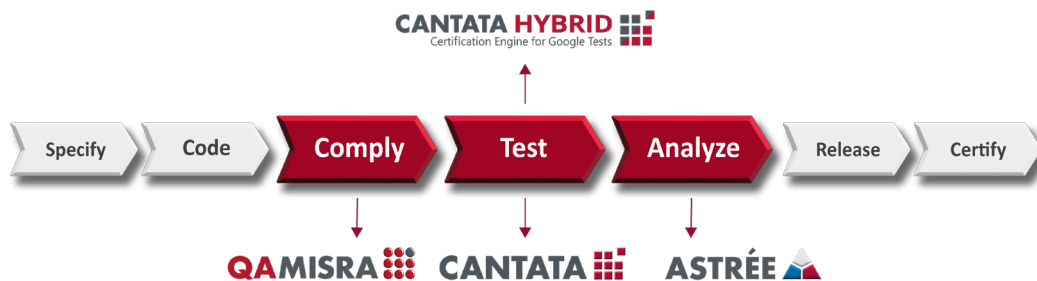
Wireless Patient Monitoring System

“We had a very positive experience with Cantata... Cantata was easier to setup than the other tools and was more feature complete... No other tool seemed to have the wrapping feature.”

Lead Developer for the EarSensor Project,
FastFocus

Standard Compliant Verification

QA Systems static analysis & software testing tools support standard compliant verification in linear flow as below:



QA Systems tools can be used for standard compliant verification to IEC 62304 (accepted by the FDA), IEC 61508 and coding standards: MISRA, CERT and CWE.

IEC 62304

IEC 62304: 2015 “Medical device software – Software lifecycle processes” is the standard which classifies and governs medical device software from safety classes A up to C. The verification techniques defined within the standard are highly reliant on automation tools qualified or certified as suitable for use (QA Systems tools are).

QA Systems tools Cantata (for unit and integration testing) and QA-MISRA (for coding standards compliant static analysis) address the processes defined in clauses: 5, 6, 8, 9 and Annex B5.5. The Cantata IEC 62304 Standard briefing and QA-MISRA Safety Manual detail how these QA Systems tools can satisfy the verification requirements of the standard.

IEC 62304 is not the most prescriptive of standards, so Annex C.7 recommends to follow the principles of IEC 61508 regarding methods, techniques and tools.

IEC 61508

The IEC 16508:2010 Functional Safety of Electrical / Electronic / Programmable Electronic Safety-related systems, Part 3 section 7.4.4 recommends that software tools are certified (QA Systems tools are certified as class T2 off-line support tools suitable for use up to SIL 4). Cantata & QA-MISRA address IEC 61508 Part 3 Software Requirements Sections 6 and 7 plus Annexes A & B. The Cantata IEC 61508 Standard briefing and QA-MISRA Safety Manual detail how these QA Systems tools can satisfy the verification requirements of this standard.



QA Systems Group
sales@qa-systems.com | www.qa-systems.com
Stuttgart, Germany | Bath, UK | Milan, Italy
Boston, US | Da Nang, Vietnam | Bengaluru, India

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Medical Devices
Customers include:



EUROIMMUN



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