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LDRA Productivity Package for Medical Devices

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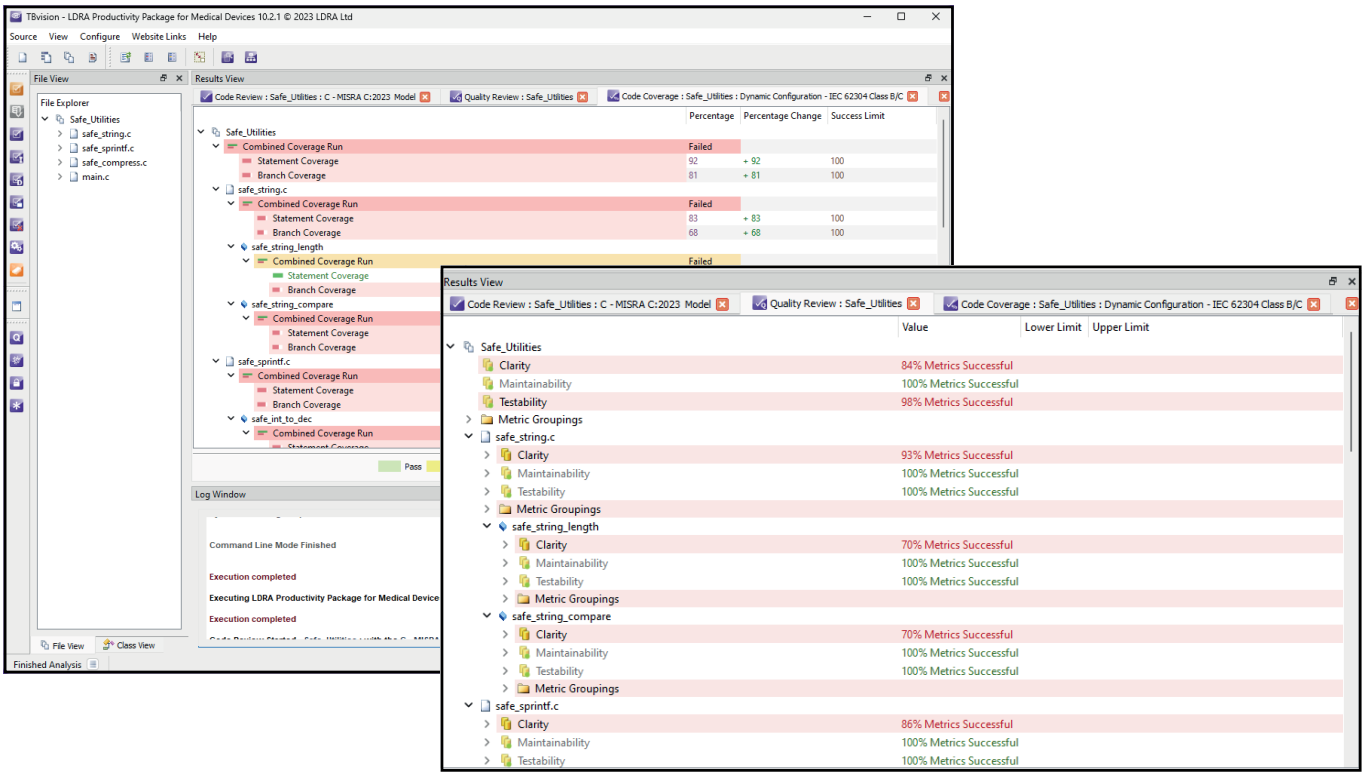
LDRA Productivity Package for Medical Devices

The LDRA Productivity Package for Medical Devices is a set of targeted capabilities drawn from the LDRA tool suite. It enables customers to meet the rigorous standards of the FDA and other regulatory authorites by achieving IEC 62304 compliance through to Class C, the highest level of assurance for medical device software. These safety focused capabilities are complemented by the tool suite's support for secure coding best practice throughout the development lifecycle.

The package includes LDRA's best in class capabilities for the development and verification of medical device software. The package's flexibility and scalability addresses the changing needs of the most demanding projects and enhances collaboration across large and small teams, making it ideal for use at any point in the software development lifecycle. The breadth of capabilities included in the package make it suitable for use in the medical devices sector, as well for the development of software to varying levels of assurance.

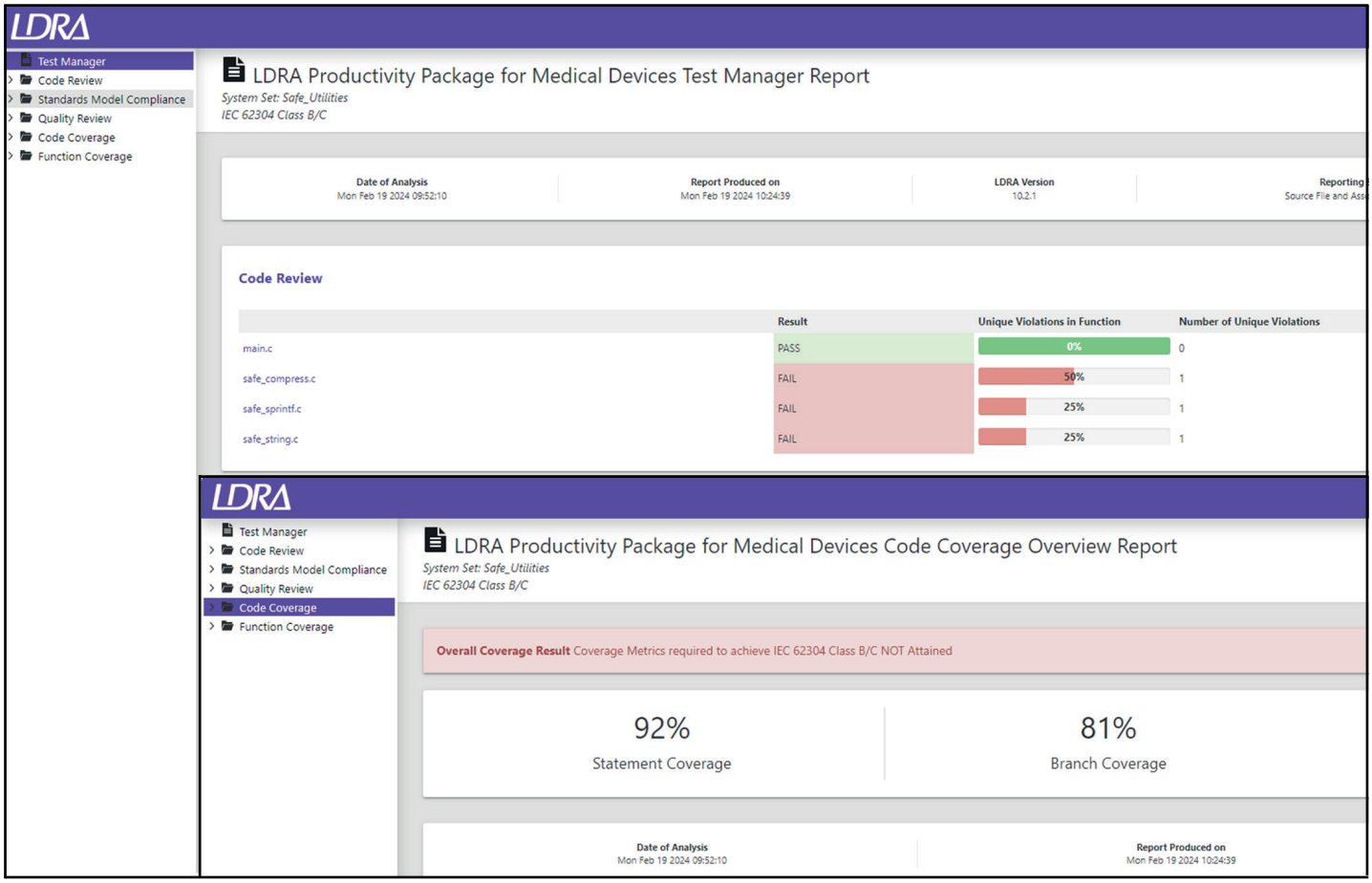
The LDRA Productivity Package for Medical Devices embraces both static and dynamic analysis techniques to encompasses a wide range of essential features designed to ensure compliance with functional safety and security standards.



Static code analysis is used to evaluate code quality and gather critical metrics. It enables checking against the rules defined by coding standards such as MISRA, CERT, and CWE, in addition to user configurable rules sets.

Dynamic analysis capabilities include unit, integration and system level testing on simulators and target hardware alike. Structural coverage analysis including MC/DC enables the assessment of coverage statistics and the implementation of requirements-based and on-target testing, while the analysis of data coupling and control coupling helps to ensure that source code is implemented in accordance with its developer's intentions.

Reporting of both static and dynamic analyses is tuned to industry requirements and formatted to reflect the objectives of IEC 62304. Optional add-on capabilities including requirements traceability, web-based project reporting of testing and analysis results, tool qualification packages, and object to source code traceability and coverage. These capabilities complement the base productivity package to provide a comprehensive toolkit for ensuring the highest level of assurance in the development of medical device software, meeting the rigorous standards of the FDA and the medical industry.



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The LDRA Productivity Package for Medical Devices at a glance:

- Functional safety compliance with IEC 62304, and validation and verification of secure coding best practice
- Static code analysis including key quality, complexity and testability metrics
- Coding standards compliance including MISRA, CERT, and CWE for both C and C++, along with many other commercially available coding standards
- The ability to define custom coding standards
- Dynamic structural coverage analysis including MC/DC
- Unit and system level testing on target hardware
- Requirements-based and on-target testing
- Security analysis and reporting, including taint analysis
- Data coupling and control coupling analysis
- Can be extended through add-on capabilities including requirements traceability, web-based project level reporting, tool qualification packages, and object to source code traceability and coverage
- Breadth of capabilities meets the needs of most medical device software development and verification projects
- Flexibility and scalability to support projects at any point in the lifecycle

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