



CASE STUDY

Inovytex Achieves FDA Certification With Customized Static Code Analysis Solution

OVERVIEW

Inovytec is an innovative medical device company that develops cutting-edge solutions for respiratory and cardiac failures. During the COVID-19 crisis, Inovytec has been a vital supplier of ventilators around the world, delivering critical care to patients suffering respiratory symptoms from the contagious disease.

The embedded development team at Inovytec delivers medical devices with safety-critical software like the Ventway Sparrow, which is a groundbreaking family of transport and emergency ventilators designed to stand up to the harshest of conditions while providing reliable high-performance ventilation at all times.

100%

**FDA 510(k)
Certification
Rules &
Guidelines**



CHALLENGE

On a mission to deliver clean code and be compliant with the FDA 510(k) regulation inspection, Inovytec started using Parasoft's C/C++ static code analysis solution.

APPROACH

To satisfy the FDA 510(k) certification, the embedded software development team customized a set of rules in Parasoft C/C++test to the standard.

"Every time we are going to release a new software version of the Ventway Sparrow ventilator, we make sure that the static analysis from Parasoft is configured to run according to the FDA regulation definitions. We not only noticed improvements in code quality, but C/C++test has really helped us in our static analysis verification activities and goal of achieving FDA 510(k) certification," said Roi Birenshtok, solution architect and team leader of embedded software.

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RESULTS

With customized C/C++ static code analysis rules, Inovytec was able to pass 100% of the FDA 510k certification rules and guidelines.

Parasoft is the testing solution of choice at Inovytec. With ESL as a distributor of Parasoft products in Israel, Birenshtok says that anytime they need help or have questions, they just call the company's managing partner, Dani Liezrowice, who takes action immediately. Inovytec appreciates the support from ESL and Parasoft.

TAKE THE NEXT STEP

Learn how your team can overcome medical device software development challenges using an integrated SDLC approach. [Download the whitepaper.](#)

ABOUT PARASOFT

[Parasoft](#) helps organizations continuously deliver quality software with its market-proven, integrated suite of automated software testing tools. Supporting the embedded, enterprise, and IoT markets, Parasoft's technologies reduce the time, effort, and cost of delivering secure, reliable, and compliant software by integrating everything from deep code analysis and unit testing to web UI and API testing, plus service virtualization and complete code coverage, into the delivery pipeline. Bringing all this together, Parasoft's award winning reporting and analytics dashboard delivers a centralized view of quality enabling organizations to deliver with confidence and succeed in today's most strategic ecosystems and development initiatives — security, safety-critical, Agile, DevOps, and continuous testing.