Rizkly

Compliance Automation for Connected Medical Devices

Build innovative medical devices with confidence. Meet EU CRA, FDA 524B and other global ICT compliance requirements — faster and easier.



Simplify Complex Requirements

End-to-end guidance & automation for EU CRA, FDA

Save Time and Resources

Built for startups without dedicated cybersecurity or compliance teams.

Reduce Risk

Identify and remediate gaps early in development.

Accelerate Time to Market

Generate audit-ready evidence and certification outputs.

Growing ICT Compliance Requirements for Medical Devices and Software

Connected medical devices combine software, cloud services, networking and 3rd-party components. US and EU regulators increasingly expect documented secure design, cybersecurity risk management, secure development, vulnerability handling and evidence that survives product changes. Rizkly helps engineering-led teams organize this work alongside development—not as a last-minute documentation scramble.

Key Requirements for Startups

EU CRA
Mandatory cybersecurity requirements for products with digital elements sold in the EU.

FDA 524B
Premarket cybersecurity documentation for applicable cyber devices in the U.S.

Global Expectations
Secure-by-design, risk management, incident reporting, transparency and ongoing post-market monitoring.

Limited Resources
Startups often lack dedicated cybersecurity and compliance staff, making automation essential.

Why It Matters

Regulatory Approval
Support market access and regulatory submissions.

Patient Safety
Reduce risks from cyber threats to patients and healthcare systems.

Business Growth
Build trust with regulators, customers and investors.

Operational Efficiency
Avoid redesigns, delays and rework later in development.

Global Market Access
Align with international cybersecurity and quality expectations.

Rizkly gives small medical device teams the tools, automation and guidance to meet today's compliance requirements while preparing to scale for tomorrow.

Rizkly

From Development to Certification - A Clear Path to Compliance

AUTOMATE
ASSURE
ACCLERATE

1 Understand Requirements

- Map product to CRA scope
- Identify applicable product categories
- Receive tailored guidance

2 Assess and Plan

- Perform cybersecurity gap assessment
- Create compliance plan and roadmap
- Assign tasks and track progress

3 Implement Controls

- Apply recommended security controls
- Manage risks and vulnerabilities
- Integrate with your development process

4 Generate Evidence

- Automatically collect evidence and logs
- Maintain design and verification records
- Create audit-ready documentation

5 Achieve and Maintain Compliance

- Support conformity assessment
- Generate certification outputs
- Continuous monitoring and lifecycle updates

How Rizkly Makes it Easy to Create & Manage Device Compliance

Proven Examples & Built-in Guidance

Device Architecture
Hardware, software, network, cloud

Risk Management Data
Threat models and risk assessments

Security Controls
Design, implementation and verification

Development Documentation
Requirements, design, testing and SBOM

Vulnerability Management
Scanning results and remediation plans

Post-Market Information
Monitoring, incidents, updates, lifecycle management

Regulatory Context
EU CRA, FDA 524B, MDR, QSR, ISO 14971

Workflow with Smart Automation

Requirements Mapping & Guidance

Automated Gap Analysis

Workflows & Task Management

Evidence Collection & Traceability

Continuous Monitoring & Regulatory Updates

Audit-Ready Reporting, Incident Response & SBOM

EU CRA Technical Documentation
Conformity evidence, security controls and lifecycle maintenance

FDA 524B Documentation
Cybersecurity plan, risk analysis, testing and validation evidence

SBOM
Published-ready software bill of materials and vulnerability tracking

Risk Management Reports
Aligned with ISO 14971 and global standards

Audit-Ready Evidence Packages
Logs, test results and traceability matrices

Regulatory Submission Support
Templates and exports for notified bodies and regulators

Ongoing Compliance Monitoring
Vulnerability alerts, change management and post-market

The Right Solution for Early-Stage Medical Device Companies

Built for Startups
Simple to adopt; no large IT or cybersecurity team required.

All-in-One Platform
Everything needed for EU CRA, FDA 524B and other global requirements.

Expert Guidance
Built-in best practices and templates from regulatory experts.

Scale with You
From development through commercialization & lifecycle management.

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