



MedCrypt

A comprehensive cybersecurity platform and consulting service for medical device manufacturers (MDMs) to secure connected devices and achieve FDA, EU MDR, and Health Canada compliance.

<https://www.medcrypt.com/>

Overview

MedCrypt is a leading cybersecurity company that provides a platform combining technology products with strategic management consulting, decision science, and regulatory strategy, all tailored for medical device manufacturers (MDMs). The company's core mission is to enable MDMs to bring innovative, life-saving connected technologies to market that are "secure by design" and comply with evolving regulations like the FDA's Section 524B.

Key Products and Capabilities

1. Guardian (Cryptography Platform):

A secure and scalable cryptographic solution that simplifies security processes and incident response. Provides automated key management, secure storage, and built-in Public Key Infrastructure (PKI). Enables secure device-to-cloud (North-South) and local network (East-West) communication with minimal performance impact. Supports secure updatability with cryptographically signed updates.

2. Helm (Vulnerability Management):

An intelligent Software Bill of Materials (SBOM) and vulnerability management solution. Automates the collection and management of SBOMs for all devices and versions, supporting open source and commercial components. Detects, prioritizes, and helps remediate cybersecurity risks by determining when vulnerabilities are relevant to a specific device.

3. Canary (Security Monitoring):

Captures medical device behavior data to provide visibility into potential security-related incidents for devices in the field, even those with limited connectivity.

4. Security Intelligence Platform:

Helps MDMs benchmark their product security posture and quantify cybersecurity financial risk in dollar terms.

Prioritizes mitigation efforts based on ROI and regulatory requirements.

Services and Regulatory Focus

MedCrypt's expert services are a critical component, offering:

Pre-Market Services: FDA cybersecurity readiness, threat modeling, PKI analysis, maturity assessments, and SDLC integration to accelerate regulatory approvals (e.g., 510(k), PMA).

Post-Market Services: Incident response, vulnerability management, risk management, SBOM validation, and regulatory change management.

Compliance: Solutions and documentation are designed to meet requirements for the FDA (including Section 524B), EU MDR, and Health Canada submissions.

MedCrypt helps MDMs avoid costly delays and re-engineering by integrating security from the start, providing automated compliance documentation, and offering expert guidance from former FDA policy experts.

Key Features

- Medical Device Cryptographic Provisioning (Guardian)
- Software Bill of Materials (SBOM) Management (Helm)
- Vulnerability Management and Prioritization
- Secure Over-the-Air (OTA) Updates
- Device-to-Cloud and Local Network Security
- Security Monitoring and Incident Response (Canary)
- Automated Compliance Documentation
- Cybersecurity Risk Quantification

Pricing

Model: subscription

Helm Standalone licensing starts at \$299 per month. Bundle Pricing (Startup to Enterprise) starts at \$32,000 per year and includes Helm 6-week trial, regulatory templates, expert advisory, and

drafting services.

Starting at: USD \$299

Target Company Size: startup, small, medium, enterprise

Integrations

RTI Connex Security Extensions, Commercial Software Composition Analysis (SCA) Tools

Compliance & Certifications

FDA (Premarket and Postmarket Guidance), EU MDR, Health Canada

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