# MedCrypt Helm

Continuous SBOM and vulnerability management platform purpose-built for medical device manufacturers to achieve FDA compliance and reduce cybersecurity risk.

https://www.medcrypt.com/

## Overview

MedCrypt Helm is an intelligent Software Bill of Materials (SBOM) and vulnerability management solution meticulously crafted for Medical Device Manufacturers (MDMs). It provides full visibility across the entire medical device software supply chain to proactively identify, prioritize, and mitigate exploitable vulnerabilities.

Born from the critical healthcare regulatory environment, Helm is specifically designed to help MDMs meet and exceed evolving mandates, including the FDA's Section 524B and the Refuse to Accept (RTA) policy under the PATCH Act. The platform is continuously refined by in-house former FDA reviewers to ensure all outputs are audit-ready and compliance-focused.

**Key Features and Capabilities:**

**FDA-Ready Compliance Reporting:** One-click generation of FDA-compliant SBOMs (CycloneDX, SPDX), VEX, and VDR reports. Historical snapshots are stored for audit-ready visibility across product versions.
**Intelligent Risk Prioritization:** Leverages medical device-specific exploitability sources (EPSS, CISA KEV, ExploitDB, Metasploit) and AI-powered intelligence to minimize false positives and focus teams on critical, exploitable vulnerabilities that impact patient safety.
**Automated Lifecycle Management:** Rules engine to automatically apply and track End-of-Life (EOL)/End-of-Support (EOS) information for components, ensuring consistency and compliance.
**Seamless Integration:** Developer-friendly API, GitHub Actions, and MS Azure DevOps integrations for continuous ingestion of SBOM updates directly into the CI/CD pipeline.
**Comprehensive Software Awareness:** Tracks open-source software (OSS), commercial third-party software, and supports Real-Time Operating Systems (RTOS).
**Automated Remediation Workflows:** Offers bulk rescoring, auto-rescoring, and import of remediation across product versions to minimize rework and ensure consistent vulnerability management at scale.
**Target Users and Use Cases:** Helm is the core tool for product security teams, regulatory affairs, and R&D engineers within Medical Device Manufacturing companies (MDMs). Primary use cases include

pre-market regulatory submission, post-market vulnerability monitoring and remediation, and overall software supply chain risk management.

## Key Features

- FDA-Ready SBOM, VEX, and VDR Reporting
- AI-Powered Vulnerability Prioritization
- Automated End-of-Life (EOL)/End-of-Support (EOS) Tracking
- CI/CD Integration (GitHub, Azure DevOps)
- Bulk Rescoring and Remediation Workflows
- Support for CycloneDX and SPDX Formats
- Real-Time Operating System (RTOS) Awareness
- Designed by Former FDA Reviewers

### Pricing

**Model:** subscription

Standalone licensing starts at $299 per month. Bundle Pricing (Startup to Enterprise) starts at $32,000/year. Bundles include a 6-week trial, regulatory templates, and expert advisory services. Additional SBOM usage may incur extra costs ($200 per additional SBOM beyond the base subscription).

**Starting at:** USD $299

**Target Company Size:** startup, small, medium, enterprise

## Integrations

GitHub Actions, MS Azure DevOps, AWS (for sending vulnerabilities), Any CI/CD pipeline via API

## Compliance & Certifications

FDA (Section 524B, PATCH Act, RTA), NTIA Minimum Requirements, EU MDR, Health Canada, Secure Product Development Framework (SPDF)