KUDELSKI IOT THINGS

FOCUS AREA

Comprehensive Security Solutions for the Medical Device Industry

We provide the services and secure foundations that will help you achieve compliance and manage your medical device throughout its entire lifetime, ensuring it continues to meet both emerging regulations and patient and provider needs.

COMPLY WITH REGULATIONS

We support Medical Device Manufacturers and Health Delivery Organizations in reaching the security objectives of key standards and regulations:

- MDR EU 2017/745
- IEC 62443-4-1
- ISO 14971
- FDA Class I, II, or III devices
- UL 2900-2-1

NAVIGATING MDM COMPLIANCE

Ensure compliance while securing your business and patients

We enable MDMs to focus on their core business while relying on our seasoned security staff for compliance and protection expertise. Achieve a trusted level of cybersecurity, manage risks, and ensure compliance with stringent and evolving regulatory requirements.

Regulatory changes

EU: Medical Device Regulation EU 2017/745 Enforced since May 2021, but grace period until May 2024

US: Section 524B of the Food & Drug Omnibus of Dec ’22 (section 3305)

Enforced from October 2023

External implications

Liabilities

Brand image

Preservation of IP value

Compliance with regulations

Internal safety needs

Patient safety

Sensitive data safety

Intellectual property

OFFERINGS

Services and solutions to secure every stage of your MDM journey

With our expertise in threat analysis, code review, device evaluation, key management, provisioning, over-the-air firmware updates, and continuous monitoring and incident response, we ensure you meet your security objectives at every phase of your medical device's product lifecycle

Premarket submission / regulations requirements

We provide the comprehensive reports and documentation of the security measures, tests, and validations performed, suitable for submission to regulatory bodies like FDA.

Threat & Risk Assessment, Code Review, Penetration Testing, Device Security Discovery.

Post-market surveillance & regulation requirements

Leverage our expertise in security, compliance and cybersecurity monitoring to help meet your PMS obligations.

Delta Code Reviews on Updates, Incident Response, Continuous Firmware Vulnerability Monitoring.

Advanced medical device security services

Enhance device security for sensitive applications, protect your valuable intellectional property and ensure the integrity of your selected components with the help of our experts.

Advanced Security Evaluation, Architecture Review, Advisory for Semiconductor BOM, IP Protection

Medical device security technologies

Our technologies enable you to securely onboard, manage, update and control your devices over-the-air, providing the protection you need to achieve protect your end-users, your brand and your revenue.

PKI, keySTREAM, Secure Provisioning, FOTA, Code Obfuscation, Secure IP

EXPERTISE & USE CASES

An active and trusted partner to the Medical Device industry

We provide comprehensive security solutions and expertise to a range of customers, including leading medical device manufacturers specializing in areas such as cardiac devices, insulin pumps, patient monitoring systems, and more.





ABOUT KUDELSKI GROUP

$100B
revenues enabled annually

500M
devices provisioned & managed

$716M
revenues (2022)

3250
employees

32
offices worldwide

70+
years of innovation