

South Korea Raises the Bar for Medical Device Cybersecurity

What Does this Mean for Global Compliance?

PITTSBURGH, PA, UNITED STATES, January 29, 2025 /EINPresswire.com/ -- Vigilant Ops, a leading provider of [SBOM lifecycle management](#), welcomes the release of South Korea's groundbreaking "Digital Medical Device Electronic Intrusion Security Guidelines" by the Ministry of Food and Drug Safety (MFDS). Effective January 24, 2025, the guidelines set a global precedent for securing digital medical devices against electronic intrusions and enhancing patient safety.



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systems, risk management throughout the product development lifecycle, and processes for vulnerability monitoring and response. These rules align closely with Vigilant Ops' mission to ensure security, compliance, and transparency in the [software supply chain](#).

Ken Zalevsky, CEO of Vigilant Ops, comments on South Korea's proactive stance on cybersecurity: "The release of these guidelines is a landmark moment for digital healthcare security. As more medical devices become interconnected, the risks of cyber threats grow exponentially. South Korea's comprehensive approach to addressing vulnerabilities and electronic intrusions sets a

standard for global regulatory efforts. At Vigilant Ops, we support manufacturers in meeting these critical requirements while protecting patients and advancing innovation."

The guidelines introduce specific requirements across several key areas, including:

- Technical Security: Encryption, input validation, and data protection measures.
- Physical Security: Access controls, secure communication channels, and system integrity.
- Vulnerability Monitoring: Continuous risk assessment and rapid response to evolving threats.

South Korea's new cybersecurity requirements signal a growing trend of stricter regulatory oversight across the globe. Countries like the U.S., through the FDA's latest guidance, and the EU, via the Medical Device Regulation (MDR), have already placed cybersecurity at the forefront of medical device compliance. South Korea now joins these efforts by prioritizing transparency and patient safety through its cybersecurity standards.

Vigilant Ops is uniquely positioned to assist manufacturers in complying with these new regulations. Through its SBOM Lifecycle Management platform, the company enables end-to-end visibility and management of software components, ensuring security throughout a product's lifecycle.

To learn more about how Vigilant Ops can help medical device manufacturers comply with South Korea's new cybersecurity requirements, visit www.vigilant-ops.com

About Vigilant Ops

Vigilant Ops is the leading platform for managing the complete Software Bill of Materials (SBOMs) lifecycle, empowering organizations to address evolving cybersecurity challenges. Our secure SaaS platform streamlines the creation, maintenance, and sharing of SBOMs, delivering robust vulnerability management and enhanced cybersecurity visibility. By simplifying complex processes, Vigilant Ops helps organizations proactively identify threats, ensure regulatory compliance, and safeguard critical systems and safety. For more information, please visit www.vigilant-ops.com. For media inquiries, please contact info@vigilant-ops.com.

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