

US Food and Drug Administration extends MoU with MedISAO for strengthening medical device security

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MedISAO, an organisation composed of members of the medical device manufacturer community dedicated to improving medical device security through education, awareness, and advocacy, has announced its endorsement by the US Food and Drug Administration (FDA) through a renewed Memorandum of Understanding (MoU), marking a continued collaboration and highlighting the importance of improving the security posture of the medical device ecosystem.

In an era where medical devices are increasingly exposed to cyber risks, a 2023 study found nearly 1,000 vulnerabilities spanning 966 medical products, highlighting the pressing need for proactive cybersecurity measures. By endorsing the partnership, the US FDA underscores the imperative continued efforts to enhance cybersecurity, uphold patient safety, and maintain care integrity over the lifetime of a device.

Medcrypt's acquisition of MedISAO in the fall of 2020 paved the way for offering the benefits of an Information Sharing and Analysis Organization (ISAO) to small and medium-sized businesses (SMBs), alongside Medcrypt's medical device security solutions, setting a precedent for pre- and post-market security measures to enhance stakeholder cooperation and safeguard patient health.

As part of the MoU with the US FDA, the partnership aims to raise awareness of cyber risk management resources produced by the Health Sector Coordinating Council (HSCC) and foster trust within the healthcare community.