AAMI TIR57 Medical Device Cybersecurity

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TIR57 Frame

AAMI TIR57 provides medical-device cybersecurity-specific risk management guidance, recognized by FDA premarket cybersecurity guidance and integrated with ISO 14971.

Architecture Implications

Cybersecurity risk management for medical devices requires structurally-supported continuous monitoring, vulnerability management, and incident response.

Architectural Mapping

Health-monitoring fleet substrate provides continuous monitoring. Governance-chain integrity supports vulnerability tracking. Cascade-propagation supports cybersecurity incident response.

Standard Evolution

TIR57 emerging revision and emerging FDA Section 524B enforcement both push toward structurally-supported architecture.