

Medical Device Adaptive Update

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What This Application Specifies

Medical-device participants integrate runtime-signed adaptation artifacts certified through sandbox pre-activation. Adaptation activations admit through composite admissibility (FDA, hospital, OEM); cascade-deactivation handles adaptation revocation or supersession; federated skill training supports cross-hospital experience integration.

Authority composition structures map to medical-device reality: FDA authority for regulatory adaptation, OEM authority for device-specific adaptation, hospital authority for institutional adaptation, professional-society authority for clinical-practice adaptation. The architecture supports the multi-authority reality of medical-device adaptation.

Why It Matters Operationally

Current medical-device adaptation depends on FDA-mandated update cycles, vendor-specific update mechanisms, and hospital-specific update procedures. The operations face structural limitations: cycle latency, vendor lock-in, audit complexity for adverse-event review.

Architectural spatial-adaptation produces structural improvement. Runtime-signed artifacts support continuous adaptation under credentialed authority; sandbox pre-

activation supports adaptation safety; cascade-deactivation supports rapid revocation.

How It Composes With the Domain

Each adaptation activation enters as a credentialed event with full FDA-aware audit lineage. Cross-hospital operations admit through declared hospital federation.

Adversarial actions (adaptation-tampering, adaptation-substitution, adaptation-integrity attacks) surface as credentialed integrity events. Federated skill training supports cross-hospital experience integration.

FDA's emerging Predetermined Change Control Plan (PCCP) framework integrates through declared admissibility profiles. Architectural adaptation supports PCCP-eligible continuous learning while maintaining structurally-supported regulatory audit.

What This Enables

Medical-device OEMs gain structurally-supported adaptive operations. Hospitals gain structurally-supported adaptation governance. FDA gains structurally-supported adaptation oversight. Patient safety gains structurally-supported audit support.

The architecture also supports medical-device evolution. As emerging medical-device adaptation patterns (AI-augmented adaptation, federated medical learning, real-world-evidence-driven adaptation, ambient-intelligence medical adaptation) mature, the architecture admits the new patterns through declared specification.

