



EU AI Act & IVDR (Medical & IVDR)

The "Notified Body" auditor is looking for high-level technical proof of safety and human control.

- **Technical Documentation (Annex II):** The core "blueprint" of how the AI was built.
- **Data Governance Policy:** Evidence of how training datasets were cleaned and checked for bias (Article 10).
- **Human Oversight Protocol:** A manual explaining how a human can override the AI's output (Article 14).
- **Instructions for Use (IFU):** The document provided to doctors/users explaining the AI's limitations.



Colorado AI Act (SB 24-205)

This auditor focuses heavily on **Duty of Care** and **Algorithmic Discrimination**.

- **Impact Assessment Report:** A study showing the AI does not discriminate against protected groups.
- **Risk Management Policy:** A formal document outlining how they identify and mitigate AI-related risks.
- **Transparency Disclosures:** The public-facing notice that tells users they are interacting with an AI.
- **Business AI Strategy:** For investment plans, proof of how AI picks stocks like **NVDA** or **PLTR**.



CMMC 2.0 / NIST 800-171 (Defense/Federal)

This is purely about **Cybersecurity** and the protection of sensitive federal data.

- **System Security Plan (SSP):** The "Holy Grail" document that describes all security controls in the company.
- **Plan of Action and Milestones (POA&M):** A list of security gaps they are currently fixing.
- **Access Control Policy:** Detailed rules on who can view Controlled Unclassified Information (CUI).
- **Incident Response Plan:** The step-by-step guide for what happens if they get hacked.

FDA PCCP

Fundamental Rights Impact Assessment (FRIA): This directly addresses the "missing assessment" gap.

Algorithm Modification Protocol (AMP): This is the FDA's term for the "Acceptance Criteria" for updates—it defines the exact thresholds the AI must meet to stay compliant.

Traceability Table: As the auditor noted, a real submission needs a table linking every code modification back to a specific safety requirement.