Elexes

FDA Cybersecurity Documentation Checklist for Medical Devices

Pre-Submission Requirements:

- Review of Device connectivity (e.g, wired, wireless, remote access)
- Comprehensive Threat modeling performed and documented
- SBOM created, listing all software components (including proprietary + 3rd party)
- Cybersecurity plan integrated into risk management plan

Cybersecurity Plan Content:

- Detailed Description of threat sources, attack surfaces, and corresponding mitigation strategies
- Description of Secure development lifecycle (SDLC)
- Testing strategy including vulnerability assessment and penetration testing
- Post-market cybersecurity management approach including update and patch strategies.

FDA-Specific Formatting:

- Documentation structured in accordance with the latest FDA premarket cybersecurity guidance Cross-referenced with IFU and product labeling
- Clearly Sectioned for integration into 510(k) or PMA submission or technical file

Final Checks:

- Reviewed by internal/external cybersecurity expert
- Prepared for submission alignment with eSTAR (if submitting digitally)
- SBOM verified for license compliance and CVE exposure

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