

MadgeTech 4 Secure Software and FDA 21 CFR Part 11

Statement On FDA Certification and Support For Electronic Records Compliance

FDA Certification and Approval

FDA does not operate a program that approves or certifies commercial software as compliant with 21 CFR Part 11. Part 11 establishes requirements for electronic records and electronic signatures used in regulated activities; it does not establish a software certification or registration pathway. Compliance depends on the implemented system, its intended use, applicable regulatory requirements, and the procedures followed by the organization using it. [1, 2]

MadgeTech 4 Secure Software is designed to aid customers in meeting 21 CFR Part 11 requirements. Its compliance support is documented through software features, product documentation, a Part 11 requirement checklist, and IQ/OQ/PQ protocols. These materials are manufacturer documentation, not an FDA approval certificate or FDA-issued letter of Part 11 compliance.

FDA may clear, approve, or otherwise authorize certain software that qualifies as a medical device under separate regulatory pathways. Such authorization is distinct from blanket certification of Part 11 compliance. Similarly, the certification submitted by users under § 11.100(c), concerning the legally binding status of electronic signatures, is a user declaration to FDA, not FDA certification of the software. [1, 3]

How MadgeTech 4 Secure Supports Compliance

MadgeTech 4 Secure provides technical controls that support a controlled electronic record environment when appropriately configured, validated, and used with customer procedures. The following summarizes documented capabilities; it is not a complete assessment of every Part 11 requirement.

Authorized access: Unique user IDs and passwords restrict access. Administrator and user permissions support control over functions and security settings. Configurable password and account controls include expiration and login lockout settings.

Audit trails: Computer-generated audit trails capture relevant software activities with user identification and date and time information. MadgeTech documentation describes secure, encrypted audit trails that can be reviewed and reproduced.

Electronic signatures: Signatures include the signer's name, signing date and time, and meaning of the signature. Signatures are linked to their records, and signing requires user credentials.

Record integrity and review: Secure proprietary files support controlled record handling. Raw datasets cannot be edited through the software; user-generated reports may be changed. Records and audit information can be printed or transferred for review.

Validation and Customer Responsibilities

IQ/OQ/PQ protocols are included with the purchase of MadgeTech 4 Secure Software. Installation Qualification, Operational Qualification, and Performance Qualification provide a structured means to document installation and operation and assess performance for the intended use. Providing protocols does not by itself validate a customer's installation. The customer must execute and approve the applicable testing, address deviations, and maintain the resulting evidence. On-site implementation support and software training are available from MadgeTech.

The regulated organization remains responsible for determining which records and activities are subject to Part 11 and the underlying FDA regulations, often called predicate rules. Its validation approach should reflect intended use and documented risk. FDA guidance describes limited enforcement discretion for certain Part 11 provisions; applicable predicate-rule obligations continue to apply. IQ/OQ/PQ alone should not be treated as a universal guarantee of compliance. [1, 2]

Customer procedures and system administration should address:

User identity verification, individual accounts, access permissions, account removal, and protection of credentials.

Training, signature accountability, and certification to FDA under § 11.100(c) when applicable.

Record and audit trail review, retention, backup, recovery, and continued availability of complete records. Required operating sequences, approved workflows, configuration and change control, and assessment of changes affecting the validated state.

The software's technical controls and the customer's documented practices work together to support compliance. A supplier statement or third-party assessment can assist a customer's evaluation, but cannot replace the customer's responsibility for its implemented system.

For More Information, please contact MadgeTech:

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References

1. 21 CFR Part 11, especially §§ 11.1, 11.10, 11.50, 11.70, 11.100 and 11.300. [View source](#)

2. FDA — Part 11 Electronic Records Electronic Signatures — Scope and Application. [View source](#)

3. FDA — Off the Shelf Software Use in Medical Devices. [View source](#)