

Upgrade your CETI8 with the 21CFR part 11 Compliance



The Cerulean's 21CFR Part 11 software upgrade for the CETI8 is now available for customers wishing to comply with 21CFR Part 11 directive - Code of Federal Regulations, title 21. The directive governs food and drug products within the US for the FDA and other agencies.

The software upgrade has a particular focus on electronic records and signatures and offers the following features and benefits.

Advantages and Features

- **Electronic signature:** Password protected access for all user groups: Supervisor, Operator, Owner IT, Servicing.
- **User Authentication:** Any one carrying out an action is recorded for full traceability of who did what and when.
- **Login controls:** Tamper secure records cannot be manipulated at a later date.
- **Version controls:** Secure record of actions, for example, newly created, modified, maintained, archived, retrieved, or transmitted.
- **Data security:** The package ensures:
 - Validation of functions relating to data integrity, security and traceability.
 - Properly functioning and well-documented instruments.
- **Audit trails:** Computer hardware and software that meets regulatory requirements as set in:

www.fda.gov/media/75414/download

Stock Code	Upgrade Option
93797	CETI8 - 21CFR part 11 for Windows 7 machines*
93798	CETI8 - 21CFR part 11 for Windows 10 machines*

* Requires installation by qualified Cerulean engineer, serial number required

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