ADVANCED CFR 21 PART 11 SOLUTION FROM SYSTEC

incl. user account management, AuditTrail, electronic data output, and signatures

SELF-SUFFICIENT CFR 21 PART 11 SOLUTION FOR MANIPULATION-SAFE AND AUTHORIZED DOCUMENTATION

no additional software needed

YOUR ADVANTAGES:

- Can be used directly: separately installed on the autoclave and therefore no separate PC software is required
- No need to validate a PC and therefore no need to update operating systems
- All data can be downloaded from the autoclave via USB or network interface* as PDF and/or CSV (Excel) files
- Automated and authorized electronic signature of PDF/CSV files. The electronic signature can be clearly traced to the respective autoclave
- Identification of valid or manipulated files
- GMP-compliant paperless documentation

*The network interface requires the optional „Save to Folder" feature for file transfer to a PC or server on the network.

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Save to Folder   OPTIONAL
The „Save to Folder" function automatically exports the current process log to the server once the program ends.
The following servers are supported: FTP, SFTP, FTPS.

THIS SOLUTION ALSO CONTAINS:

User control:
With the advanced user contorol, up to 100 groups and 100 users can be freely managed for preset groups & users (3 preset groups, each with one user: administrator, operator, supervisor). The administrator receives the corresponding additional authorizations.
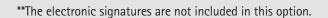
AuditTrail:
AuditTrail enables chronological documentation of changes to the system or process activities over time. All events with or without authorization requests are saved in the AuditTrail. This includes all user events as well as service and system events.

Electronic data output:
Electronic data output contains a digital signature to ensure the authenticity of the data. The signature's authenticity can be verified in the PDF file via Adobe Reader or in the CSV file via OpenSSL.

Electronic signatures:
Up to 5 fields for electronic signatures** to sign the exported PDF or CSV files on a PC (or another device with the ability to sign documents electronically). All exported data (batch logs, audit trail, error memory, process memory) are signed in a manner secure against forgery according to the X.509 standard.

Examples of user events:
- Create, change, activate, deactivate, unlock users / groups / programs
- Change program parameters
- Change passwords
- Acknowledge error messages

PDF   CSV

PDF

**The electronic signatures are not included in this option.