
Self-declaration

MCOSMOS and FDA 21 CFR Part 11

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We confirm:

Using any release version of our CMM software versions

- MCOSMOS v3.1, v3.2, v3.3, v3.4, v3.5
- MCOSMOS v4.0, v4.1, v4.2

within additional customer specified processes makes it possible to fulfil the rules of the FDA guideline 21 CFR Part 11.

In the above mentioned MCOSMOS versions the following functionality is available to fulfil the rules of the FDA guideline 21 CFR Part 11:

- ⇒ User and access control including all requirements of password handling
- ⇒ Revision management system for measurement programs, global subprograms and report templates including a modification history (audit trail)
- ⇒ Forgery-proofed measurement reports in PDF format



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