

CDMS 2022.5 Release Certificate

Document Version: 1.0

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Release Certificate Acceptance

This is to certify that the CDMS version 2022.5. has successfully passed validation and is approved for release. Proper usage of the software enables users to be EU Annex 11 and FDA 21 CFR Part 11 compliant.

As part of the validation effort, the following documentation was produced.

Validation Documentation
CDMS 2022.5 Validation Plan
CDMS 2022.5 System Requirement Document
CDMS 2022.5 System Design Document
CDMS 2022.5 Test Cases/Results (In TestRail)
CDMS 2022.5 Validation Summary Report
CDMS 2022.5 Release Notes (online)
CDMS 2021.x 21 CFR Part 11 Statement of Compliance
CDMS 2022.5 Installation Qualification Operational Qualification
CDMS 2021.x 21 CFR Part 11 Traceability Matrix

Castor successfully completed the validation effort and associated documentation and considers this a validated release. The details of the validation effort are documented in the CDMS 2022.5 Validation Summary Report. The major release was assessed for compliance with 21 CFR Part 11 and GCP.

Documentation for the previously mentioned deliverables are maintained electronically in Castor's QISMS portal and can be reviewed during audits or scheduled review sessions upon client request.

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