

EDC 2021.5 Release Certificate

Document Version: 1.0

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Release Certificate Acceptance

This is to certify that the system Castor EDC version 2021.5 has successfully passed installation qualification, operational qualification and performance qualification 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
EDC 2021.5 Validation Plan
EDC 2021.5 System Requirement Document
EDC 2021.5 System Design Document
EDC 2021.5 Test Cases/Results (In TestRail)
EDC 2021.5 Validation Summary Report
EDC 2021.5 Release Notes (online)
EDC 2021.x 21 CFR Part 11 Statement of Compliance
EDC 2021.5 Installation Qualification Operational Qualification
EDC 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 EDC 2021.5 Validation Summary Report. The major release was assessed for compliance with 21 CFR Part 11.

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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The signatures below indicate that the validation criteria is acceptable.

QA Approval	DocuSigned by: <i>Ben Driesen</i>  Signer Name: Ben Driesen Signing Reason: I approve this document Signing Time: 12-Oct-2021 9:03:20 AM CEST 2EE2C77E7DD94FFC8D17A479F833A09D
Name and Title	Ben Driesen, Manager of QA

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