

Castor Connect 2022.1 Release Certificate

Document Version: 1.0

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Release Certificate Acceptance

This is to certify that the system Castor Connect version 2022.1 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
Castor Connect 2022.1 Validation Plan
Castor Connect 2022.1 System Requirement Document
Castor Connect 2022.1 System Design Document
Castor Connect 2022.1 Test Cases/Results (In TestRail)
Castor Connect 2022.1 Validation Summary Report
Castor Connect 2022.1 Release Notes (online)
Castor Connect 2021.x 21 CFR Part 11 Statement of Compliance
Castor Connect 2022.1 Installation Qualification Operational Qualification
Castor Connect 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 Castor Connect 2022.1 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	<p>DocuSigned by: <i>Ben Driesen</i></p> <p> Signer Name: Ben Driesen Signing Reason: I approve this document Signing Time: 11-Apr-2022 8:11:00 AM CEST 2EE2C77E7DD94FFC8D17A479F833A09D</p>
Name and Title	Ben Driesen, Manager of QA

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