

eConsent 2021.4 Release Certificate

Document Version: 1.0

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Release Certificate Acceptance

This is to certify that the system eConsent version 2021.4.
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
eConsent 2021.4 Validation Plan
eConsent 2021.4 System Requirement Document
eConsent 2021.4 System Design Document
eConsent 2021.4 Test Cases/Results (In TestRail)
eConsent 2021.4 Validation Summary Report
eConsent 2021.4 Release Notes (online)
eConsent 2021.x 21 CFR Part 11 Statement of Compliance
eConsent 2021.4 Installation Qualification Operational Qualification
eConsent 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 eConsent 2021.4 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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The signatures below indicate that the validation criteria is acceptable.

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Name and Title	Marta Ornelas Mauricio, QA Engineer

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