

eConsent 2022.1 Release Certificate

Document Version: 1.0

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Release Certificate Acceptance

This is to certify that the system eConsent 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
eConsent 2022.1 Validation Plan
eConsent 2022.1 System Requirement Document
eConsent 2022.1 System Design Document
eConsent 2022.1 Test Cases/Results (In TestRail)
eConsent 2022.1 Validation Summary Report
eConsent 2022.1 Release Notes (online)
eConsent 2021.x 21 CFR Part 11 Statement of Compliance
eConsent 2022.1 Installation Qualification Operational Qualification - EU
eConsent 2022.1 Installation Qualification Operational Qualification - US
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 2022.1 Validation Summary Report. The major release was assessed for compliance with 21 CFR Part 11 and GCP.

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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.

The signatures below indicate that the validation criteria is acceptable.

QA Approval	<div><div>DocuSigned by: <i>Marta Rodrigues Ornelas Mauricio</i> Signer Name: Marta Rodrigues Ornelas Mauricio Signing Reason: I approve this document Signing Time: 08-Mar-2022 11:08:24 AM CET 2CC97C3A8B5A4D5AA4C4A667E6BF0730</div></div>
Name and Title	Marta Ornelas Mauricio, QA Lead

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