eConsent v2022.5.0.0
Release Certificate

Document Version: 1.0

Release Certificate Acceptance

This is to certify that the system eConsent version v2022.5.0.0 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
Validation Plan
Test Cases/Results (In TestRail)
Validation Summary Report
System Requirements Document/System Design Document
Release Certificate
Installation Qualification/Operational Qualification - EU
Installation Qualification/Operational Qualification - US

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 v2022.5.0.0 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.

The signatures below indicate that the validation criteria is acceptable.

QA Approval	DocuSigned by: Yauheni Bryliou Signer Name: Yauheni Bryliou Signing Reason: I am the author of this document Signing Time: 15-Dec-2022 | 2:15:10 PM CET 32E232FA23FF4E9DAD59C7FA6E56FD33
Name and Title	Yauheni Bryliou, QA Engineer