

eConsent 2024.1.0.0 Release Certificate

Document Version: 1.0

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Release Certificate Acceptance

This is to certify that the eConsent version 2024.1. has successfully passed validation 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 Notes (online)

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 2024.1.0.0 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.

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QA Approval	DocuSigned by: <i>Marta Rodrigues Ornelas Maurício</i>  Signer Name: Marta Rodrigues Ornelas Maurício Signing Reason: I approve this document Signing Time: 06-Mar-2024 2:51:36 PM CET 2CC97C3A8B5A4D5AA4C4A667E6BF0730
Name and Title	Marta Rodrigues Ornelas Maurício QA Lead

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Envelope Id: 994E47DAD4B84F09953E6AF4A4A86DF3	Status: Completed
Subject: Complete with DocuSign: eConsent 2024.1.0.0Release Certificate.pdf	
Source Envelope:	
Document Pages: 3	Signatures: 1
Certificate Pages: 5	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelopeld Stamping: Disabled	Marta Rodrigues Ornelas Maurício
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna	George Westinghousestraat 2
	Amsterdam, Amsterdam 1097 BA
	marta@castoredc.com
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Status: Original	Holder: Marta Rodrigues Ornelas Maurício	Location: DocuSign
3/6/2024 2:45:50 PM	marta@castoredc.com	

Signer Events

Signer Events	Signature	Timestamp
Marta Rodrigues Ornelas Maurício marta@castoredc.com QA Lead Security Level: Email, Account Authentication (Required)	<i>Marta Rodrigues Ornelas Maurício</i> Signature Adoption: Pre-selected Style Signature ID: 2CC97C3A-8B5A-4D5A-A4C4-A667E6BF0730 Using IP Address: 178.132.215.44 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 3/6/2024 2:50:13 PM Viewed: 3/6/2024 2:51:17 PM Signed: 3/6/2024 2:53:14 PM

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ID: c5145cb2-c1c5-4dfc-8c61-ce82a3f8ec01

In Person Signer Events

Signature	Timestamp
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Editor Delivery Events

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Status	Timestamp
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Intermediary Delivery Events

Status	Timestamp
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Certified Delivery Events

Status	Timestamp
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Carbon Copy Events

Status	Timestamp
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Witness Events

Signature	Timestamp
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Notary Events

Signature	Timestamp
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Envelope Summary Events

Status	Timestamps
Envelope Sent	Hashed/Encrypted 3/6/2024 2:50:13 PM
Certified Delivered	Security Checked 3/6/2024 2:51:17 PM
Signing Complete	Security Checked 3/6/2024 2:53:14 PM
Completed	Security Checked 3/6/2024 2:53:14 PM

Payment Events

Status	Timestamps
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