

# How does Castor protect your data?



Data integrity and transparency are the key attributes of everything we do at Castor. We are committed to protecting our customers' data above all else. At Castor, our Quality and Information Security Management System (QISMS) ensures global regulatory compliance and robust data protection for our customers and employees.

## Security highlights

- ▶ Compliant with ISO standards (ISO/IEC ISO 27001 ISO 27001/ IEC 27001/NEN 7510/ISO 9001 and Dutch NEN 7510 certified)
- ▶ Application code uses modern techniques to minimize the risk of SQL injection, cross site scripting (XSS) and other common attacks.
- ▶ Immutable audit logs provide a fine-grained overview of data access and modifications.
- ▶ Data is encrypted at rest and in transit.
- ▶ Continuous Penetration Tests ensure our application and infrastructure security is always up to date.
- ▶ Users have individual accounts and strong passwords are required. Users are locked out of their account after 10 failed login attempt.
- ▶ Sessions automatically time out after 20 minutes of inactivity.
- ▶ Institute administrators can enforce additional security policies, such as mandatory two-factor authentication or regular password rotation.
- ▶ Backups are made twice daily and stored encrypted within a different physical location to ensure maximum security and continuity.
- ▶ An additional layer of encryption is available to optimize data security.
- ▶ Castor applications run on fully managed virtual servers on [Microsoft Azure](#) in the following regions:
  - EU: region EU West (Netherlands) and EU North (Ireland)
  - UK: region UK South (London) and UK West (Cardiff)
  - AU: region Australia East (New South Wales)
  - US: region US East (Virginia) and US West (California)
- ▶ Network security groups and firewalls ensure that no unauthorized connections can be made to any of our servers. [Read about how we protect data.](#)

# Quality and Information Security Management System

Castor's QISMS is based on the [ISO/IEC 27001](#) and [ISO 9001](#) standards.

In line with GXP and 21 CFR Part 11 requirements, the QISMS involves a number of policies and procedures around validation, change management, backup and restore, disaster recovery, audits, supplier management, CAPA management, risk assessment and risk treatment, and [Infrastructure Security for applications](#).



## Castor is compliant with the following regulations and guidelines:

- ▶ Food and Drug Administration (FDA) 21 CFR Part 11: Electronic Records; Electronic Signatures; Final Rule
- ▶ FDA Guidance for Industry 21 CFR Part 11: Electronic Records; Electronic Signatures – Scope and Application
- ▶ FDA Guidance for Industry and FDA Staff: General Principles of Software Validation
- ▶ FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations
- ▶ FDA: Title 21 CFR [Good Clinical Practices](#)
- ▶ International Conference on Harmonization (ICH), E6 Guideline for Good Clinical Practice and Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)
- ▶ Good Automation Manufacturing Practices (GAMP) 5
- ▶ FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format
- ▶ EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 11: Computerised Systems
- ▶ Health Information Portability and Accountability Act (HIPAA)
- ▶ PIC/S Guidance on Good Practices for Computerized Systems in Regulated “GxP” Environments
- ▶ [General Data Protection Regulation \(GDPR\) \(EU\) 2016/679](#)



## Software Development Life Cycle (SDLC)

The SDLC for Castor products is based on industry standard agile methodology. The following deliverables are produced for major releases:

- ▶ Validation Plan
- ▶ System Requirement Document
- ▶ System Design Document
- ▶ Validation Summary Report
- ▶ Traceability Matrix
- ▶ Release Certificate
- ▶ IQ/OQ
- ▶ 21 CFR Part 11 Statement of Compliance

[Release Notes](#) are posted online describing new features and functionality, enhancements, and bug fixes.

## Customer success

The customer success team is available to provide world-class support to all Castor users, via the dedicated support email and the helpdesk web chat function. Learn how to get the most out of Castor products and find all compliance client facing deliverables through the [Knowledge Base](#).

## Questions?

▶ CONTACT US