Computerized Systems Compliance Statement

(EU GMP - Annex 11 Alignment)

for the Cure Puck

Client:

Company Name

1. Purpose and Scope

This document describes how the Cure Puck system aligns with relevant principles of EU Good Manufacturing Practice (GMP) for computerized systems, as outlined in EudraLex Volume 4, with specific reference to Annex 11 - Computerized Systems.

The Cure Puck is intended as a monitoring and data acquisition tool used within regulated manufacturing environments. This statement is provided to support customer supplier qualification activities.

2. System Description

Cure Puck is a monitoring system that captures process and environmental data and presents this information to users for operational visibility. The system does not perform automated product release decisions or quality determinations.

3. Regulatory Positioning

Cure Puck is not positioned as the GMP system of record.

Keirton does not claim Annex 11 certification or validation.

Final responsibility for GMP compliance rests with the regulated manufacturer, in accordance with EU GMP requirements.

4. Data Access and Export

Data generated by Cure Puck is available to the customer for export in non-proprietary CSV format.

Export functionality enables customers to:

- Retain local copies of GMP-relevant data
- Integrate data into validated internal systems
- Perform independent backup, archival, and restore testing

This design supports Annex 11 principles for data availability and long-term retention under customer control.

5. Data Integrity and Security

Logical access controls are implemented to restrict system access to authorized users.

Data is protected against unauthorized modification during normal operation.

The cloud infrastructure hosting Cure Puck data operates within a SOC 2 Type II audited environment, providing assurance of security, availability, and confidentiality controls at the infrastructure level.

6. Data Retention

Operational Cure Puck data is retained within the hosted environment for 12 months in accordance with the service's standard retention policy, while the service remains active.

Customers remain responsible for ensuring that their overall data retention period meets applicable GMP and regulatory requirements, including retention beyond the platform's standard retention period where required.

7. Backup and Restore Responsibilities

Cure Puck enables data export but does not act as the authoritative archive for GMP records.

Responsibility for the following resides with the regulated manufacturer:

- Defining record retention requirements
- Performing backups
- Verifying restore capability
- Ensuring data availability for inspections

This responsibility allocation is consistent with Annex 11 expectations for computerized systems where third-party tools are used.

8. Change Management

Changes to the Cure Puck system are managed by Keirton under internal development and release controls.

Customers are responsible for assessing the impact of system updates on their validated state and GMP processes.

9. Supplier Responsibility Model

Area	Responsibility

Hardware device functionality	Keirton
Application software	Keirton
Cloud infrastructure security and operational controls	SOC 2 Type II audited provider
GMP validation	Customer
Data backup and archival	Customer
Data restore testing	Customer

10. Conclusion

Cure Puck is designed to support use in GMP-regulated environments by enabling controlled data access, export, and customer-managed retention. When used within a properly validated customer framework, the system can be incorporated into GMP operations in alignment with Annex 11 principles.