# Clarity GAMP software categorization certificate

## Software identification

- Software Name: **Clarity**

- Vendor: DataApex Ltd.

- Software Type: Chromatography Data System (CDS)

- Category Classification: GAMP Category 4 - Configured Software

## GAMP category 4 classification

This certificate confirms that **Clarity** software from DataApex Ltd. has been evaluated and classified as **GAMP Category 4: Configured Software** in accordance with **ISPE GAMP 5** guidelines.

### Category 4 Definition

Configured software is a software package that has been configured to meet user requirements without modification of the vendor's source code. Configuration involves selecting and setting parameters, options, and preferences within the software's standard functionality.

### Justification for Category 4 Classification

The Clarity software qualifies as GAMP Category 4 based on the following characteristics:

- **Commercial Off-The-Shelf (COTS) Software:** Clarity is a commercially available software package developed and maintained by DataApex Ltd.

- **Configuration-Based Implementation:** The software is implemented through configuration of existing functionality rather than custom programming or source code modification.

- **Established Vendor:** DataApex Ltd. is an established vendor with documented software development practices and quality management systems.

- **Regulatory Compliance Features:** The software includes built-in features designed to support pharmaceutical and regulatory compliance requirements.

- **Standard Functionality:** Implementation utilizes standard, documented features and functions provided by the vendor.

## Validation implications

As GAMP Category 4 software, Clarity requires:

- **Vendor Assessment**: Evaluation of DataApex Ltd.'s software development practices and quality management system

- **Risk Assessment**: Analysis of intended use and associated risks

- **Installation Qualification (IQ**): Verification of proper software installation

- **Operational Qualification (OQ):** Testing of configured functionality

- **Performance Qualification (PQ)**: Verification that the system meets user requirements in the intended environment

- **Documentation:** Comprehensive documentation of configuration, testing, and validation activities

*This document is prepared in accordance with ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems.*