

Declaration of Software Validation

Structural validation and Statement of compliance with 21 CFR Part 11

Release Date: 2024-03-19

Product Name: Clarity Chromatography Station

Version Number: 9.1.00.076

This document certifies that the software was developed, tested, and structurally validated following a Certified Quality System conforming to GLP, GAMP, GMP, and ISO 9001 Guidelines. This product was found to meet all functional and performance specifications and product release requirements. Software Life Cycle checkpoints were reviewed and approved by management.

To support this certificate for GLP/GMP requirements of the user of this product, we will make the following outputs of the Standard Development Life Cycle available to customers and an authorized authority for inspection at DataApex Ltd., Prague (Czech Republic):

- Description of the product
- Functional specification
- Development plan
- Test plan, routines, and result
- Revision Status
- Source code documentation

DataApex will maintain this documentation, including software source code, on-site and at a secure off-site location. DataApex may require a non-disclosure agreement to be provided by those wanting access to the information.

21 CFR Part 11 Compliance Features:

This software has been developed and tested in a manner consistent with the requirements for validation and operation in FDA-regulated industries. It incorporates features that can provide technical compliance with 21 CFR Part 11 when implemented and operated in accordance with that regulation. The product description and functional specification contain information related to the inclusion of the 21 CFR Part 11 feature set. The Test Plan, Test Procedures, and Test Data Demonstrate how these features were evaluated.

21 CFR Part 11 Compliance Features include Software Security, Data Integrity, Audit Trails, Controls, and Electronic Signatures. These features are briefly elaborated in the datasheet D019.

The Clarity in Regulated Environment manual (M132) provides detailed procedures on how to set the station in order to comply with the regulations.

Prague, 19.3.2024

Jan Hruby,



General Manager

DataApex