

ZETASIZER (NANO, μ V, APS) SOFTWARE: v8.01

CERTIFICATE OF CONFORMANCE

We hereby certify that the above referenced software has been developed, tested and released in conformance with Malvern Panalytical's ISO9001:2015 procedures. These are maintained as part of Malvern Panalytical's:

- Software Development Process
- ISO 9001:2015 Quality Management System
- ISO 14001:2015 Environmental Management System
- ISO45001:2018 H&S Management System

These procedures provide a fundamental basis for an end user's validation of the software and include the production of documentation tracing the conformance of the software to design requirements in accordance with GAMP guidelines. This documentation is open to inspection as part of a paid audit.

The following items are available to help Quality Assurance personnel to complete the validation of their Zetasizer (NANO, μ V, APS) systems:

- Installation Qualification and Operational Qualification procedures.
- A 21 CFR Part 11 Feature Key providing users with access to software features designed to aid technical compliance to the requirements of 21 CFR Part 11.
- A 21 CFR Part 11 Guide offering guidance regarding how the software can be configured within a 21CFR11 compliant environment.
- A comprehensive Regulated Environment Compliance Test Schedule providing a series of tests which may be used to validate the software's 21CFR Part 11 features and correct installation and set-up.

Approvals		
Role	Name	Signature
Acceptance	Steve Anderson	
Approval	James Wraight	
Release	Darrell Bancarz	
Release Date:	17/09/2020	

Please Note:

The Scope of the assurance offered by this Certificate is limited to Malvern Panalytical Documentary Procedures only. The issue of this certificate does not relieve users of their ultimate responsibilities for validation of 3rd Party Software used by them.