


Mastersizer Software: v4.01

Certificate of Conformance

We hereby certify that the above referenced software has been developed, tested and released in conformance with Malvern Panalytical's ISO 9001:2015 procedures. These are maintained as part of Malvern Panalytical's:

- Software Development Process
- ISO 9001:2015 Business Management System
- ISO 14001:2015 Environment Management System
- ISO 45001:2018 Occupational H&S Management System
- ISO/IEC 27001:2013 Information Security (with respect to Malvern Panalytical Cloud Services)

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.

Approvals		
Role	Name	Signature
Approval	Nicholas Borton Chief Software Engineer	
Release Date:	08/09/2023	

The following items are available to help Quality Assurance personnel complete the validation of their Mastersizer Software systems:

- Installation Qualification and Operational Qualification procedures.
- An OmniTrust License Key providing users with access to software features designed to aid technical compliance to the requirements of 21 CFR Part 11.
- A Regulated Environment Guide offering guidance regarding how the software can be configured within a 21 CFR Part 11 compliant environment.
- A regulated environment compliance test document providing a series of tests which may be used to validate the software's 21 CFR Part 11 features.

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.



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