

MASTERSIZER 3000: v3.50 software

CERTIFICATE OF CONFORMANCE

WITH VALIDATION PROCEDURES



PARTICLE SIZE

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We hereby certify that the above referenced software has been developed, tested and released in conformance with Malvern Instruments' ISO9001:2008 and TickIT plus compliance procedures. These are maintained as part of Malvern's:

- Software Development Process
- ISO 9001:2008 Business Management System
- ISO 14001:2004 Environment Management System
- OHSAS 18001:2007 H&S Management System

These procedures define Malvern's Design Qualification (DQ) process, providing a fundamental basis for an end user's validation of the software. This includes 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 users to complete the validation of their Mastersizer 3000 systems:

- Installation Qualification and Operational Qualification procedures, covering both hardware and software qualification in line with USP<1058> requirements;
- 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 21CFR Part 11 compliant environment;
- Gap analysis documents relating to 21CFR Part 11 and EU Annex 11 requirements;
- A 21 CFR Part 11 Test Schedule providing a series of tests which may be used to validate the Mastersizer 3000 software's 21CFR Part 11 features.

Approvals

Role	Name	Signature
Acceptance	Paul Kippax Product Owner	
Approval	Steve Anderson Chief Engineer	
Release	Simon Wihl Engineering Manager Software	
Release Date:	22/03/2016	

Please Note: This certificate relates to Malvern Instrument's business management systems only. It does not cover any validation procedures implemented by the end user of the software.