

MASTERSIZER 3000: v3.30 software

Certificate of Conformance with Validation Procedures



PARTICLE SIZE

Malvern Instruments Ltd

Enigma Business Park
Groewood Road
Malvern.
Worcestershire UK. WR14 1XZ

Tel: +44 (0)1684 892456
Fax: +44 (0)1684 892789

Malvern Instruments Worldwide

Sales and service centers in
over 50 countries.

For details visit
www.malvern.com/contact

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more information at
www.malvern.com

We hereby certify that the above referenced software has been developed, tested and released in conformance with Malvern Instruments' ISO9001:2008 and TickITplus 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 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 Mastersizer 3000 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 21 CFR Part 11 Test Schedule providing a series of tests which may be used to validate the software's 21CFR Part 11 features.

Stephen Anderson
Chief Engineer

Simon Wihl
Software Manager

A. BUCKMASTER

Paul Kippax
Product Manager

Date: May 27, 2015

Please Note:

The Scope of the assurance offered by this Certificate is limited to Malvern 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.