

Mastersizer 2000 Version 5.60 Software (PSS0002-31)

Certificate of Conformance with Validation Procedures

We hereby certify that the above-referenced software has been developed, tested and released in conformance with Malvern Instruments' ISO9001: 2000 and TickIT compliance procedures.

These procedures, which provide a fundamental basis for the end user's validation of the software, have included the production of the following documentation tracing the conformance of the software to design requirements, in accordance with GAMP guidelines:

Lifecycle Documentation:

Requirements Specification
 Functional Specification
 Design Specification
 Design Test Schedules and Reports
 Alpha test documentation
 Beta test documentation

Malvern Instruments Codes of Practice:







Software Development Codes Of Practice
 ISO 9001:2000 Business Management System
 ISO 14001 Environmental Management System
 Design Change Management System
 Management Procedures Manual

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 2000 systems:

- **Installation Qualification (IQ) procedures**
- **Operational Qualification (OQ) procedures**
- **21 CFR Part 11 feature keys** providing users with the means to achieve technical compliance to 21 CFR Part 11.
- **21 CFR Part 11 Test Scripts**
- **IQ/OQ Preview and Validation Planning Folder**
- **Software Update Verification** procedures
- **User Requirements Specification Matrix**

Please Note: The scope of the assurance offered by this certificate is limited to Malvern Instruments' documented procedures only. The issue of this certificate does not diminish the responsibility of users to carry out their own validation of the software.

   ISO 9001:2000 The TickIT Guide Issue 5	Date: 05 January 2010  Steve Anderson, Chief Engineer
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