

Malvern Version 5.40 Software for the Mastersizer 2000

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 ISO9000: 2001 and TickIT Compliance Procedures.

These procedures which provide a fundamental basis for the end user's Validation of the software has 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 and Protocols:

Software Development Codes Of Practice
 ISO 9000:2001 System
 Design Change Management System
 Management Procedures Manual

The validation of this software is further supported by the following QSpec Validation Elements:

QSE2012 21 CFR Part 11- enabling feature key package

As well as a feature key to enable the 21 CFR Part 11- compliant features of the software, this package includes **MAL2140 IQ/OQ**

Preview and Validation Planning Binder which includes the following sections:

- 21 CFR Part 11 Test Script
- ER/ES Compliance Check and User Advice
- Details of Software Numerical Validation
- User Requirements Specification Matrix
- Generic Audit Q&A and details of Audit options






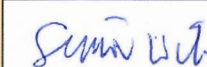
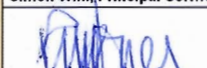
ATM2000 Alpha Test Matrix

This is a separately available item describing all the functions of the software and detailing the tests applied, together with confirmation of the outcome of the tests.

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.

   ISO 9001:2000 The TickIT Guide Issue 5	Date: 23 rd January 2007
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