## Malvern Version 5.13 Particle Sizer 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:* | *Malvern Instruments Codes of Practice and Protocols:* |
| --- | --- |
| *Requirements Specification* | *Software Development Codes Of Practice* |
| *Functional Specification* | *ISO 9000:2001 System* |
| *Design Specification* | *Design Change Management System* |
| *Design Test Schedules and Reports* | *Management Procedures Manual* |
| *Alpha test documentation* | |
| *Beta test documentation* | |

**Rights to view this documentation under the terms of a non-disclosure agreement are available as an option in the Malvern Instruments QSpec Validation Elements programme.**

The QSpec Validation Elements programme includes the following ***separately*** available items to help Quality Assurance personnel to complete the full validation of their Mastersizer 2000 systems:

- **Installation Qualification/ Operational Qualification (IQ/OQ )**
- **IQ/OQ Preview and Validation Planning Folder**
- **Software Update Verification**
- **Escrow Licenses**
- **QSpec Elements Rights-to-View Certification and Registration**

*Includes the provision of a Logbook which acts as a validation Workbook for individual Mastersizer installations*

- **User Requirements Specification Matrix**

*This is a detailed specification of the Mastersizer 2000 describing the system and its capabilities and detailing pass/fail criteria which can form the basis of a User Performance Qualification.*
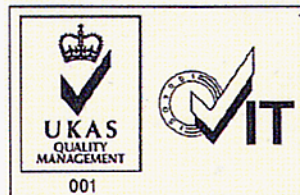
- **21 CFR Part 11 Feature Keys**

*These provide users with the technical means to achieve 21CFR Part 11 compliance.*

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.

INSTRUMENTS WITH THIS VERSION OF SOFTWARE INSTALLED WILL PRODUCE PRINTED REPORTS WITH THE CORRESPONDING SOFTWARE VERSION AND THE INSTRUMENT SERIAL NUMBER EMBEDDED IN THE FOOTER.

**MALVERN INSTRUMENTS**

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QUALITY
MANAGEMENT
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**IT**

**ISO 9001:2000**
*The TickIT Guide Issue 5*

Date: 30th March 2004

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