

Malvern Version 5.10 Software for the Zetasizer Nano Series of Instruments

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

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

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