

Malvern V7.01 Software for the Zetasizer 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 ISO9001: 2008 and The TickIT Guide Issue 5.5.

These procedures, which provide a fundamental basis for the end user's Validation of the software, include 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 9001:2008 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.



Malvern



ISO 9001:2008

The TickIT Guide Issue 5.5

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