

Malvern V6.32 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.



*ISO 9001:2008
The TickIT Guide Issue 5.5*

Date: 8 th November 2011
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