

# MASTERSIZER 3000

Mastersizer 3000 Version 2.10 Software

## 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 TickIt compliance procedures.

These procedures, which provide a fundamental basis for an 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:

Software Development Codes Of Practice  
ISO 9001:2008 Business Management System  
ISO 14001:2004 Environment Management System  
OHSAS 18001:2007 H&S Management System

This documentation is open to inspection as part of a paid audit.

The following items are available to help Quality Assurance personnel to complete the validation of their Mastersizer 3000 systems:

- **Installation Qualification** and **Operational Qualification** procedures.
- A **21 CFR Part 11 Feature Key** providing users with access to software features designed to aid technical compliance to the requirements of 21 CFR Part 11.
- A **21 CFR Part 11 Guide** offering guidance regarding how the Mastersizer 3000 software can be configured within a 21CFR11 compliant environment.
- A **comprehensive 21 CFR Part 11 Test Schedule** providing a series of tests which may be used to validate the software's 21CFR Part 11 features.

### Please Note:

The scope of the assurance offered by this certificate is limited to Malvern Instruments' documentary procedures only.

The issue of this certificate does not relieve users of their ultimate responsibilities for validation of 3<sup>rd</sup> party software used by them.


  
**Malvern**



ISO 9001:2008

The TickIT Guide Issue 5.5

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