

# MASTERSIZER 3000

Mastersizer 3000 Version 1.11 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 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.

### Malvern Instruments Codes of Practice and Protocols:

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.




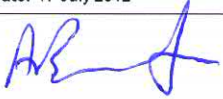


The following items are available to help Quality Assurance personnel to complete the validation of their Spraytec systems:

- Installation Qualification/ Operational Qualification (IQ/OQ)
- 21 CFR Part 11 Feature Key providing users with the means to achieve technical compliance to the requirements of 21 CFR Part 11.
- 21 CFR Part 11 Guide offering guidance regarding how the Mastersizer system can be configured within a 21CFR11 compliant environment.

### 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 3<sup>rd</sup> Party Software used by them.

   ISO 9001:2008 The TickIT Guide Issue 5.5	Date: 17 July 2012
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