

# Spraytec: v3.30 software

## CERTIFICATE OF CONFORMANCE

### with Validation Procedures



**PARTICLE SIZE**

We hereby certify that the above referenced software has been developed, tested and released in conformance with Malvern Instruments' ISO9001:2008 and TickIT Plus compliance procedures. These are maintained as part of Malvern Instrument's:

- Software Development Process
- ISO 9001:2008 Business Management System
- ISO 14001:2004 Environment Management System
- OHSAS 18001:2007 H&S Management System

These systems define Malvern's Design Qualification (DQ) process, providing a fundamental basis for an end user's validation of the software. This includes documentation tracing the conformance of the software to design requirements in accordance with GAMP guidelines. This documentation is open to inspection as part of a paid audit.

The following items are available to help user complete the validation of their Spraytec systems:

- Installation Qualification and Operational Qualification procedures, covering system qualification in line with USP<1058> requirements;
- 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 software can be configured within a 21CFR Part 11 compliant environment;
- A 21 CFR Part 11 compliance guide, explaining how the Spraytec software meets the requirements of 21 CFR Part 11;
- A 21 CFR Part 11 Test Schedule providing a series of tests which may be used to validate the Spraytec software's 21CFR Part 11 features.

**Malvern Instruments Ltd**

Enigma Business Park  
 Grovewood Road  
 Malvern.  
 Worcestershire. UK. WR14 1XZ

Tel: +44 (0)1684 892456  
 Fax: +44 (0)1684 892789

**Malvern Instruments Worldwide**

Sales and service centers in over 65 countries.

For details visit [www.malvern.com/contact](http://www.malvern.com/contact)

© Malvern Instruments Ltd 2015

more information at [www.malvern.com](http://www.malvern.com)

Approvals		
Role	Name	Signature
Acceptance	Paul Kippax Product Owner	
Approval	Steve Anderson Chief Engineer	
Release	Simon Wihl Principal Software Engineer	
Release Date:	01/12/2015	

# CERTIFICATE OF CONFORMANCE

**Please Note:** This certificate relates to Malvern Instrument's business management systems only. It does not cover any validation procedures implemented by the end user of the software.