

Spraytec Version 3.10 Software (PSS0024-09)

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 ISO9000: 2001 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.

<p>Lifecycle Documentation: <i>Requirements Specification</i> <i>Functional Specification</i> <i>Design Specification</i> <i>Alpha test documentation</i></p>	<p>Malvern Instruments Codes of Practice and Protocols: <i>Software Development Codes Of Practice</i> <i>ISO 9000:2001 System</i> <i>Design Change Management System</i> <i>Management Procedures Manual</i></p>
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This documentation is open to inspection as part of a paid audit.





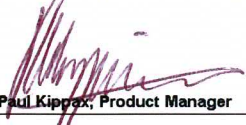
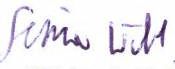
The following items are available to help Quality Assurance personnel to complete the validation of their Spraytec systems:

- **Installation Qualification/ Operational Qualification (IQ/OQ)**
- **21 CFR Part 11 Feature Keys** providing users with the means to achieve technical compliance to the requirements of 21 CFR Part 11
- **21 CFR Part 11 Guides** offering guidance regarding how the Spraytec 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 3rd Party Software used by them.

 Malvern   ISO 9001:2000 The TickIT Guide Issue 5	Date: 13 August 2009 
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