

MORPHOLOGI G3

Software Suite PSS0025-22 (v7.42)

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: 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 9000:2008 System
Business 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 Morphologi systems:

- **Installation Qualification/ Operational Qualification (IQ/OQ)**
- **21 CFR Part 11 Feature Keys** providing users with the technical means to achieve 21 CFR Part 11 compliance

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.

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|  MALVERN INSTRUMENTS | Date: 21 st June 2012 |
|  UKAS QUALITY MANAGEMENT 001 | Andy Buckmaster, Project Manager  |
|  TICKIT | Simon Wihl, Design Authority  |
| ISO 9001:2008 The TickIT Guide Issue 5.5 | Andy Mackenzie, Technical Authority  |