MORPHOLOGI

Morphologi Version 7.43 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.

Software Development Codes Of Practice
ISO 9001:2008 System
ISO 14001:2004 Environmental 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 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
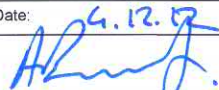
Please Note:
The Scope of the assurance offered by this Certificate is limited to Malvern Documentary Procedures only.

The issue of this certificate does not relieve users of their ultimate responsibilities for validation of 3rd Party Software used by them.

Malvern

UKAS
QUALITY
MANAGEMENT
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TickIT

ISO 9001:2008
The TickIT Guide Issue 5.5

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