

# MORPHOLOGI

## Morphologi Version 8.11 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.

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



ISO 9001:2008  
The TickIT Guide Issue 5.5

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A.J. Pison Pete Moore: Project Manager, P.P. Imaging
 Ben Pattison: Engineering Manager, Imaging
 Simon Wihl: Engineering Manager, Software