

Certificate of Conformance

OmniTrust Compliance toolkit (incl. OmniAccess and OmniTrail)

We hereby certify that the referenced software has been developed, tested and released in conformance with Malvern Panalytical's procedures. These are maintained as part of Malvern Panalytical's:

- Software development process
- ISO9001:2015 certificate
- ISO14001:2015 certificate

These procedures provide a fundamental basis for an end user's validation of the software and include the production of 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 QA personnel complete the validation of the Malvern Panalytical instruments:

- Installation Qualification and Operational Qualification procedures.
- An OmniTrust license key providing additional components and enabling software features designed to aid technical compliance to the requirements of a regulated environment (21 CFR Part 11).
- A regulated environment guide offering guidance regarding how the software can be configured within a 21 CFR Part 11 compliant environment.
- A regulated environment compliance test document providing a series of tests which may be used to validate the software's 21 CFR Part 11 features.

The items above are applicable to the following instruments:

- Aeris
- Empyrean
- Zetasizer Advance
- Mastersizer 3000

8 August 2023



Folkert Homma
Product Safety and Compliance Director – Malvern Panalytical