



Malvern Panalytical
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Chamber of Commerce
Enschede 06069492

Certificate of Conformance

Data Collector, HighScore (Plus), Data Viewer and OmniTrust software

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 instrument Empyrean.

- 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.

Almelo, 11 June 2021

A handwritten signature in blue ink, appearing to be 'Folkert Homma', written in a cursive style.

Folkert Homma
Director of Product Safety and Compliance