MALVERN ACCESS CONFIGURATOR: v2.10 software
CERTIFICATE OF CONFORMANCE
with Validation Procedures

PARTICLE SIZE

MOLECULAR SIZE

MOLECULAR WEIGHT

MOLECULAR STRUCTURE

RHEOLOGICAL PROPERTIES

LABEL FREE BINDING

MICROCALORIMETRY

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We hereby certify that the above referenced software has been developed, tested and released in conformance with Malvern Instruments' ISO9001:2008 and TickIT Plus compliance procedures. These are maintained as part of Malvern's:

- Software Development Process
- ISO 9001:2008 Business Management System
- ISO 14001:2004 Environment Management System
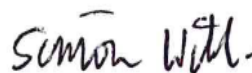- OHSAS 18001:2007 H&S Management System

These procedures define Malvern's Design Qualification (DQ) process, providing a fundamental basis for an end user's validation of the software. This includes the production of documentation tracing the conformance of the software to design requirements in accordance with GAMP 5 guidelines. This documentation is open to inspection as part of a paid audit.

The Malvern Access Controller is designed to be installed with the application software provided with Malvern's Mastersizer 3000, Kinexus, OMNISEC and PEAQ-DSC instruments. The following items are available to help users to complete the validation of these instruments:

- Installation Qualification and Operational Qualification procedures, covering both hardware and software qualification in line with USP<1058> requirements;
- A 21 CFR Part 11 Feature Key providing users with access to software features designed to aid technical compliance to the requirements of 21 CFR Part 11;
- A 21 CFR Part 11 Guide and Gap Analysis offering guidance regarding how Malvern software can be configured within a 21CFR Part 11 compliant environment;
- A Malvern Access Configurator manual, providing advice on configuring and deploying a security system;
- A 21 CFR Part 11 Test Schedules providing a series of tests which may be used to validate a software's 21CFR Part 11 features.

Steve Anderson	Simon Wihl	Paul Kippax
Chief Engineer	Software Manager	Product Manager

Date: July 27, 2017

Please Note: This certificate relates to Malvern Instrument's business management systems only. It does not cover any validation procedures implemented by the end user of the software.

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