

Validation of Malvern Version 5.11 Particle Sizer Software for the Mastersizer 2000

DISCLAIMER:

*OWING TO THE FDA'S STIPULATION THAT VALIDATION OF 3RD PARTY SOFTWARE IS THE RESPONSIBILITY OF **USERS**, IT IS NOT POSSIBLE TO PROVIDE A CERTIFICATE OF VALIDATION THAT WILL ABSOLVE USERS OF THIS RESPONSIBILITY.*

FOR THIS REASON, THIS DOCUMENT IS LIMITED TO DESCRIBING THOSE MEASURES THAT HAVE BEEN TAKEN BY MALVERN INSTRUMENTS TO ASSIST THEIR CUSTOMERS IN CARRYING OUT THE VALIDATION OF THEIR SOFTWARE SYSTEMS.

The above-referenced software has been subjected by Malvern Instruments to a formal process of verification steps to thoroughly test the correct performance of the code.

This process has included the production of a complete set of Lifecycle Documentation tracing the conformance of the software to design requirements in accordance with GAMP guidelines.

Rights to view the supporting documentation are available as an option in the Malvern Instruments QSpec Validation Elements programme to assist users with the Design qualification of their systems.

The QSpec Validation Elements programme includes the following **separately** available items to help Quality Assurance personnel to complete the validation of their Mastersizer 2000 systems:

- **Installation Qualification/ Operational Qualification (IQ/OQ)**
- **Software Update Verification**
- **Escrow Licenses**
- **QSpec Elements Rights-to-View Certification and Registration**
Includes the provision of a Logbook which acts as a validation Workbook for individual Mastersizer installations
- **User Requirements Specification Matrix**
This is a detailed specification of the Mastersizer 2000 describing the system and its capabilities and detailing pass/fail criteria which can form the basis of a User Performance Qualification.
- **Standards**
Latices for the Performance Verification of Mastersizer optical benches
Quality Audit Standards for the Performance Verification of sample dispersion units
- **21 CFR Part 11 Feature Keys**
These provide users with the means to achieve 21 CFR Part 11 compliance.

For further information concerning the validation of your Malvern laser diffraction particle size analyser, please contact your local Malvern office.