



Validation of Malvern Version 3.01 Particle Sizer Software for the Mastersizer 2000

The above-referenced software has been validated by a formal process of verification steps to prove 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 guidelines established by the pharmaceutical industry.

Access to the supporting documentation is available as a right to view under the terms of Malvern Instruments' optional QSpec Validation Contract which has been designed to provide a comprehensive validation package for those of our users who must comply with the requirements of the FDA, MCA and other Regulatory Authorities.

Other items supplied under the terms of the QSpec Contract include the following:

- *The performance of the system IQ/OQ and the provision of specifications and reports.*
- *A right to view the Lifecycle documentation relating to the system hardware.*
- *A right to view relevant portions of the developers' resumé's.*
- *A right to view the source code.*
- *A right of access to the source code held in escrow.*
- *A report detailing the complete software verification procedure.*
- *An optional right to view the performance of the software verification procedure.*

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