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SOFTWARE STRUCTURAL VALIDATION CERTIFICATE
(GMP / ISO 9001)
& Statement of Compliance to 21 CFR Part 11
Pyris Software Version 5.0

This product was developed using the English language version of Microsoft® Windows® 2000 and structurally validated following a Certified Quality System conforming to GMP and ISO 9001 requirements.

A Standard Development Life Cycle has been followed which conforms to the ISO 9001 Standard.

The output of this Life Cycle includes the following documents.

- The Product Description
- The Software Quality Plan
- The Functional Specification
- The Test Plan
- The Test Procedures and Test Data
- The Software Release Notice and Revision Control
- The Source Code Documentation

The existence of these documents and the procedures used in their production are formal requirements of the PerkinElmer Quality System. The integrity of this PerkinElmer Quality System is routinely audited and is certified by the British Standards Institution as meeting all the requirements of ISO 9001, the internationally recognized standard for Quality Assurance.

Note: PerkinElmer retains possession of all documents; their reproduction—including parts thereof.

Optional Enhanced Security software package

The Product Description and Functional Specification contains detailed information relative to the inclusion of 21 CFR Part 11 features. The Test Plan, Test Procedures and Test Data demonstrate how these features were evaluated.

This 21 CFR Part 11 feature set contains:

User Level Management

Security controls through different access permissions.

File Integrity

Electronic records are secured, versioned, and tampered files are detected.

Audit Trails

Automatic generation of secure time-stamped audit trails for all record changes (data, calibration, method, and system).

Electronic Signatures

User-definable electronic signature with customizable reasons list.

Systems Quality Assurance Manager
PerkinElmer - Shelton, Connecticut

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