



Declaration of System Validation

We herewith inform you that the software product/system

Product number: G3025A

Product name: Agilent Technologies 5100 Automated Lab-on-a-Chip Platform Expert HT software with user license

Revision number: A.01.2x

was developed according to the quality process and software life cycle followed by the Life Science and Chemical Analysis divisions of Agilent Technologies. Life cycle check-point details were reviewed and approved by management. The product was found to meet its functional and performance specifications, and release criteria at release to shipment.

In order to fulfill the validation requirements of the users of this product according to current regulations and quality standards excluding 21 CFR 210 (Good Manufacturing Practice for Drugs), 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals),

Agilent Technologies will maintain possession of all documents and their reproductions and may require a confidential disclosure agreement to be provided by those requiring access to these documents.

Date: January, 2005

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- ☒ **Product description**
Specifications
- ☒ **Lifecycle Phase Transition Approvals**
Proposal
Investigation
Design
Implementation
Test
Manufacturing Release
- ☒ **Software Quality Assurance**
Quality Plan
Release criteria
Software Test Plan
Test procedures and acceptance criteria
Definition of expected test results
Test cases, test suites, test results
System change request tracking and reporting
- ☒ **Documentation and Change Management**
Requirements Management
Software Configuration Management
Change Management Process
Coding Standards
- ☒ **Source Code**



G3025-90500

P/N G3025-90500

