

## Declaration of Software Validation

We herewith inform you that the software product/systems listed in the table below were 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 products were 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 including, but not limited to, 21 CFR 210 (Good Manufacturing Practice for Drugs), 21 CFR 211 (current Good Manufacturing Practice for finished pharmaceuticals), 21 CFR 58 (Good Laboratory Practice). Agilent Technologies will make the source code and the documents referenced on [page 2](#) of this declaration available to an authorized governmental or regulatory agency for inspection at its Santa Clara, California site (terms and conditions to be negotiated). 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.

Product name	Product number	Revision number
OpenLAB Data Store for MS	M8623AA	A.01.03

Date: July 3, 2013

Quality Manager:



John Lindahl  
Quality Manager, PLLI  
Agilent Technologies, Inc.

- Product Description**
  - Specifications
  
- Lifecycle Phase Transition Approvals**
  - Proposal
  - Investigation
  - Implementation
  - Test
  - Manufacturing Release
  
- Software Quality Assurance**
  - Quality Plan
  - Release Criteria
  - Software Test Plan
  - Test Procedures
  - Test Results
  - Test traceability to requirements
  - System change request tracking and reporting
  
- Documentation and Change Management**
  - Requirements Management
  - Software Configuration Management
  - Coding Standards
  
- Source Code**



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