

# **Declaration of Software Validation**

We herewith inform you that the software product/system

Product Name	Product Number	<b>Revision Number</b>
EZChrom Elite	G6711AA, G6712AA, G6700AA, G6701AA,	3.3.2 SP1
	G6704AA, G6705AA	
EZChrom SI	G6702AA, G6703AA, G4679AA, G4680AA	3.3.2 SP1
	G2801A Opt. 610	
	G2802A Opt. 610	
	G2805A Opt. 610	

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 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 facility (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.

Date: August 20, 2009

**Quality Manager:** 

the the

John Lindahl Quality Manager 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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