

Certificate of Compliance



Certificate Number: 13CA55205

Applicant/Manufacture: BGI Tech Solutions CO., LTD

Address: 201, Science and Innovation Park, Main Building, Beishan Industrial Zone

Product Name: BMS Production Management System

Regulation: U.S.FDA 21 CFR Part 11

Technical File: Please refer to the attachment.

Product description:

The BMS Production Management System is applied on the entire process of Next Generation Sequencing from sample receiving to report submission. The system keeps records of essential information of each stage to realize the monitoring of Next Generation Sequencing process. Meanwhile it can generate the testing report automatically.

Conclusion:

This is to certify that the product complies with all relevant provisions of the U.S.FDA 21 CFR Part 11. This certificate is only valid for the technical file, equipment and configuration described above.

Certificate issued by:

A handwritten signature in blue ink that reads 'Tim Lin'.

Tim Lin

Engineering Leader

Greater China, MRAS, UL Health Sciences

Date of Issue: May 13, 2014

Any significant changes in design or construction of the product, or amendments to the Standards referenced above may render this receipt invalid. The product liability rests with the manufacturer or his representative in accordance with U.S.FDA 21 CFR Part 11.

While all due care and skill was exercised in carrying out this assessment, UL Health Sciences accept responsibility only for proven gross negligence. This certificate is issued for the date that the product was validated. Conformance to all regulation requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products.

This is not legal document and cannot be used as such. This certificate remains the property of UL Health Sciences to whom it must be returned on request.

UL Medical Regulatory Advisory Services

No: 13CA55205

Attachment

List of Technical File

- **Quality Manual & Organization Chart**

BGI-TS-01-01 the management handbook for environment, occupational health & safety and information security

- **SOP Index**

- **Computer System SOPs & IT Change SOP & Configuration Management SOP**

BGI-TS-03-24-01-003 Testing Design management protocol

BGI-TS-03-24-01-004 Software requirement change management protocol

BGI-TS-03-24-01-007 Software development outsourcing management protocol

BGI-TS-03-24-02-001 Software development project protocol

BGI-TS-03-24-02-002 Requirement analysis SOP

BGI-TS-03-24-02-003 Concept development SOP

BGI-TS-03-24-02-004 Development SOP

BGI-TS-03-24-02-005 Alpha testing SOP

BGI-TS-03-24-02-006 Beta testing SOP

BGI-TS-03-24-02-010 Controlled access SOP

- **Security and Access Control SOP**

BGI-TS-03-24-04-002 BMS system authorization application procedure

BGI-TS-04-24-04-001 Form of BMS system authorization application

- **Computer System Backup and Restore SOP & Disaster Recovery, Business Continuity Plan & Archive of Data SOP**

BGI-CP -SOP14 -008 Operation/maintenance group SOP

BGI-IST-03-R02-018 Business continuity plan

BGI-TS-03-24-03-006 BMS disaster recovery procedure

BGI-TS-03-24-03-008 BMS Restore Test SOP A0

BGI-TS-03-24-03-009 Data backup SOP A0

BGI-TS-04-24-03-009 Restore Test Checklist

BGI-TS-04-24-03-010 Data backup Record

Attachment

- **Vender Management SOP**

BGI-QP-14 Vender management procedure

- **Validation Master Plan & Computer System Validation Documentation**

001_Software, Firmware Information

002_Software Hazard Analyses

003_Software Requirement Specification

004_Software Design Specification

005_Software Verification and Validation

BGI-TS-04-24-01-001 Software requirement List

BGI-TS-04-24-01-002 Project instruction

BGI-TS-04-24-01-003 Software requirement analysis instruction

BGI-TS-04-24-01-004 Preliminary design instruction

BGI-TS-04-24-01-005 Software testing plan

BGI-TS-04-24-01-006 Software testing cases

BGI-TS-04-24-01-007 Detail design instruction

BGI-TS-04-24-01-008 User Manual

BGI-TS-04-24-01-009 Maintenance Manual

BGI-TS-04-24-01-011 Acceptance Report

BGI-TS-04-24-01-012 Project Summary Report

BMS1.1.0 Project testing report

- **Documentation Management SOP**

BGI-QP-01 Documentation management procedure

- **Human Resource Training SOP**

BGI-QP-07 Human Resource Training procedure

- **Electronic Signature**

BGI-TS-03-24-04-003 BMS Electronic Signature Application Procedure A1

BGI-TS-04-24-04-002 BMS Electronic Signature Form