

# Certificate of Compliance



**Certificate Number: 13CA55205-02**

**Applicant/Manufacture:** BGI Tech Solution (HONGKONG) CO., LIMITED

**Address:** 16 Dai Fu Street, Tai Po Industrial Estate, Tai Po, New Territories, Hong Kong

**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:**

Based upon the Declaration of Conformity as attachment, BGI Tech Solution Co., Ltd. Wuhan adopts identical BMS Production Management System from BGI Tech Solutions Co., Ltd. The BMS Production Management System of BGI Tech Solutions Co., Ltd. is compliance with U.S. FDA 21 CFR Part 11. The number of certification is 13CA55205.

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**

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