

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 2037350-1

Organization: Wuhan MGI Tech Co., Ltd.  
Building 24, Stage 3.1, BioLake  
Accelerator, No.388, 2nd Gaoxin Road,  
East Lake High-Tech Development Zone,  
430075, Wuhan,  
P.R. China

Scope: Manufacture and Distribution of Genetic Sequencing Reagents and  
Reagent Kits, Genetic Sequencing Instruments, Sample Preparation  
Instruments and Auxiliary Devices, Circulating Tumor Cells (CTC)  
Enrichment Instruments for IVD Diagnosis, Robotic Ultrasound Systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10917211-100

Effective date: 2020-12-14

Expiry date: 2023-07-27

Issue date: 2020-12-14

A circular seal for TÜV Rheinland LGA Products GmbH, featuring a stylized 'A' logo and the text 'TÜV Rheinland LGA Products GmbH' and 'Tillystraße 2 · 90431 Nürnberg · Germany'.

Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following:

No.	Facility	Scope
/01	Wuhan MGI Tech Co., Ltd. Building B13, No.818, Gaoxin Avenue, East Lake High-Tech Development Zone, 430075, Wuhan, P.R. China	Manufacture of Genetic Sequencing Reagents and Reagent Kits, Genetic Sequencing Instruments, Sample Preparation Instruments and Auxiliary Devices, Circulating Tumor Cells (CTC) Enrichment Instruments for IVD Diagnosis, Robotic Ultrasound Systems

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