

# ISO 13485



## Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Ustar Biotechnologies  
(Hangzhou) Co., Ltd.  
3766 Nanhuan Rd. Fl 8  
Binjiang Dist.  
Hangzhou  
310053 Zhejiang  
China**

has established and applies a quality management system for medical devices  
for the following scope:

**Manufacture and Distribution of Nucleic Acid Diagnostic  
Test Kits, Isothermal Amplification Multi-segment Magnetic  
Nucleic Acid Analyzers  
(see attachment for additional sites included)**

Proof has been furnished that the requirements specified in

### EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-09-18  
Certificate Registration No.: SX 60129670 0001  
An audit was performed. Report No.: 15068133 006  
This Certificate is valid until: 2020-05-18

Certification Body



Date 2018-09-18



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