



# Certificate

No. Q5 108683 0001 Rev. 00

**Holder of Certificate:** **Guangdong Wesail Biotech Co., Ltd.**  
2F, Building 1, 5 Hualian Street  
Songshan Lake Science and Technology Industrial Park  
Songshan Lake  
523808 Dongguan, Guangdong  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In vitro diagnostic kit for Infectious disease, Cardiac markers, Diabetes, Renal Injury, Tumor marker, Thyroid, Pregnancies, Anemia, Bone Metabolism, Hormone and Quality Control reagents, Immunofluorescence Analyzer, and Incubator**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 108683 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_108683_0001_Rev.00)

**Report No.:** GZ2055001

**Valid from:** 2020-10-13  
**Valid until:** 2023-10-12

**Date,** 2020-10-13



Christoph Dicks  
Head of Certification/Notified Body



Product Service

# Certificate

No. Q5 108683 0001 Rev. 00

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Guangdong Wesail Biotech Co., Ltd.  
2F, Building 1, 5 Hualian Street, Songshan Lake Science and  
Technology Industrial Park, Songshan Lake, 523808 Dongguan,  
Guangdong, PEOPLE'S REPUBLIC OF CHINA