



Product Service

# Certificate

No. Q5 061788 0009 Rev. 03

**Holder of Certificate:** **Shenzhen Kang Sheng Bao Bio-Technology Co., Ltd.**

Second Floor, Block 3  
An Da Electronic Industrial Park, Fu Hai  
Bao An District  
518103 Shenzhen, Guangdong Province  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, Sales and Distribution of In Vitro Diagnostic Kits of Infectious Immunology, Cardiac Markers, Tumour Markers, Hormone Series Markers.**

**Design and Development, Production, Sales and Distribution of In Vitro Diagnostic Instruments for Immunochemistry.**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 061788 0009 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_061788_0009_Rev_03)

**Report No.:** GZ2412603

**Valid from:** 2025-04-01

**Valid until:** 2028-03-31

**Date,** 2025-02-13

Christoph Dicks  
Head of Certification/Notified Body



Product Service

# Certificate

No. Q5 061788 0009 Rev. 03

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Shenzhen Kang Sheng Bao Bio-Technology Co., Ltd.**  
Second Floor, Block 3, An Da Electronic Industrial Park, Fu Hai,  
Bao An District, 518103 Shenzhen, Guangdong Province,  
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate