



# Certificate

No. Q5 048128 0076 Rev. 03

**Holder of Certificate:** **Hangzhou Bioer Technology Co., Ltd.**  
1192 BinAn Rd, Binjiang District  
310053 Hangzhou  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Production and Distribution of Clinical Diagnostic Lab Instruments and In Vitro Diagnostic Reagents Based on Molecular Biology Techniques**

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 048128 0076 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_048128_0076_Rev._03)

**Report No.:** SH2209801

**Valid from:** 2022-05-01

**Valid until:** 2025-04-30

**Date,** 2022-04-26



Christoph Dicks  
Head of Certification/Notified Body

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**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):** Hangzhou Bioer Technology Co., Ltd.  
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