



Product Service

# Certificate

No. Q5 077434 0014 Rev. 01

**Holder of Certificate:** **HANGZHOU BIOTEST BIOTECH CO., LTD.**

17#, Futai Road, Zhongtai Street  
 Yuhang District  
 311121 Hangzhou  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development,  
 Production and Distribution of  
 In Vitro Diagnostic Kit for the Detection of  
 Hormone, Drug of Abuse,  
 Infectious Disease,  
 Tumour Marker and Cardiac Marker**

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). See also notes overleaf.

**Report No.:** SH1970812

**Valid from:** 2019-12-18

**Valid until:** 2020-09-05

**Date,** 2019-12-18

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 BIOTEST BIOTECH CO., LTD.  
17#, Futai Road, Zhongtai Street, Yuhang District, 311121  
Hangzhou, PEOPLE'S REPUBLIC OF CHINA

CITUS DIAGNOSTICS INC.  
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