



Product Service

# Certificate

No. Q5 042074 0031 Rev. 01

**Holder of Certificate:** **Acon Biotech (Hangzhou) Co., Ltd.**

No.210 Zhenzhong Road  
West Lake District  
310030 Hangzhou  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Acon Biotech (Hangzhou) Co., Ltd.  
No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou,  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

**Design and Development,  
Production and Distribution of  
In Vitro Diagnostic Test Kits  
and Related Instruments,  
Lancet and Lancing Device**

**Applied Standard(s):**

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

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.:** SH1910622

**Valid from:** 2019-07-15

**Valid until:** 2022-07-14

**Date,** 2019-07-09

Stefan Preiß  
Head of Certification/Notified Body