



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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE ◆

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