ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 077434 0014 Rev. 02

Holder of Certificate: **HANGZHOU BIOTEST BIOTECH CO., LTD.**
17#, Futai Road, Zhongtai Street
Yuhang District
311121 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

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,
Bacterial Vaginosis PH Panel(Vaginal Discharge)**

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.: SH2070801

Valid from: 2020-09-06
Valid until: 2023-09-05

Date, 2020-07-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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D-ZM-11321-01-00

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No. Q5 077434 0014 Rev. 02

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.
300-422 Richards street, Vancouver, British Columbia V6B 2Z4,
CANADA

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