



Product Service

CERTIFICATE

No. Q5 17 06 77434 014

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

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

Facility(ies):

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**

**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.: SH1770810

Valid from: 2017-09-06

Valid until: 2020-09-05

Date, 2017-07-18

Stefan Preiß



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