



Certificate

No. Q5 085542 0011 Rev. 01

Holder of Certificate:

Chaozhou Hybribio Biochemistry Ltd.

D5-3-3-4, High And New Area

Economic Development Experimental Zone

521000 Chaozhou, Guangdong PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Sample Collection Kit Series,

Nucleic Acid Extraction Kit Series,

GenoArray Diagnostic Kit Series, Real-time

PCR Diagnostic Kit Series

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.:

GZ1909201

Valid from:

2020-01-10

Valid until:

2023-01-09

Date,

2020-01-03

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):

Chaozhou Hybribio Biochemistry Ltd.

D5-3-3-4, High And New Area, Economic Development

Experimental Zone, 521000 Chaozhou, Guangdong, PEOPLE'S

REPUBLIC OF CHINA

Chaozhou Hybribio Biochemistry Ltd.

4th floor, Building B D5-5 District, High and New Area, Economic Development Experimental Zone, 521000 Chaozhou, Guangdong,

PEOPLE'S REPUBLIC OF CHINA