



Product Service

Certificate

No. Q5 059892 0010 Rev. 03

Holder of Certificate: **Maccura Biotechnology Co., Ltd.**
16#, Baichuan Road, Hi-tech Zone
611731 Chengdu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Clinical Chemistry, immunochemistry, Infectious diseases, Haemostasis, Haematology and Genetic Testing**

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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 059892 0010 Rev. 03

Report No.: SH2448802

Valid from: 2024-12-01
Valid until: 2027-11-30

Date, 2024-11-19

Christoph Dicks
Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Maccura Biotechnology Co., Ltd.**
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REPUBLIC OF CHINA

See Scope of Certificate