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

TÜV SÜD
Product Service

Certificate

No. Q5 106272 0001 Rev. 00

Holder of Certificate: **Zhuhai Encode Medical Engineering Co., Ltd**
NO. 020, Honghui 2nd Rd
Hongqi Industrial Zone, Jinwan District
519090 Zhuhai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of in Vitro Diagnostic Rapid Test for the Detection of Fertility, Drugs of Abuse, Cardiac Markers, Tumor Markers, Infectious Diseases, Sexually Transmitted Disease, including professional use, near patient and self testing, Microbiological Diagnostic Kit and related instruments, Immunofluorescence Analyzer and Immunofluorescence Reagents**

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 106272 0001 Rev. 00

Report No.: GZ1942801

Valid from: 2021-05-11
Valid until: 2024-05-10

Date, 2021-05-11

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

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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):

Zhuhai Encode Medical Engineering Co., Ltd
NO. 020, Honghui 2nd Rd, Hongqi Industrial Zone, Jinwan District,
519090 Zhuhai, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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