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

Product Service

Certificate

No. Q5 105335 0001 Rev. 00

Holder of Certificate: **Zhejiang Quark Biotechnology Co., Ltd.**
No.1 Jiangdong Road
Zhejiang Xinchang High-tech Industrial Park
Xinchang District
312500 Shaoxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Zhejiang Quark Biotechnology Co., Ltd.
No.1 Jiangdong Road, Zhejiang Xinchang High-tech Industrial Park, Xinchang District, 312500 Shaoxing, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In-Vitro Diagnostic Kit based on Immunochromatography method for Fertility, Infectious Disease, Drug of Abuse, Cardiac Markers**

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.: SH19156801

Valid from: 2020-02-10
Valid until: 2023-02-09

Date, 2020-02-10

Christoph Dicks
Head of Certification/Notified Body

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

A4 / 07.17

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

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