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

Product Service

Certificate

No. Q5 063367 0018 Rev. 02

Holder of Certificate: **Nantong Egens Biotechnology Co., Ltd.**
Building 15, Building 12 (west)
No. 1692 Xinghu Avenue
Nantong Economy & Technology Development Zone
226010 Nantong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV
SÜD
EN ISO 13485
tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution
of Rapid Test Kit for the Detection of Fertility Function
Hormones, Pregnancy, Tumor Markers, Drugs of Abuse,
Infectious Disease, Sperm Concentration and Clinical
Chemistry, Blood Glucose Monitoring System**

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 063367 0018 Rev. 02

Report No.:   SH22241A01

Valid from: 2022-09-01
Valid until: 2025-08-31

Date,   2022-09-01

Christoph Dicks
Head of Certification/Notified Body

TÜV®

Certificate

No. Q5 063367 0018 Rev. 02

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):
Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west), No. 1692 Xinghu Avenue,
Nantong Economy & Technology Development Zone, 226010
Nantong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Rapid
Test Kit for the Detection of Fertility Function Hormones,
Pregnancy, Tumor Markers, Drugs of Abuse, Infectious Disease,
Sperm Concentration and Clinical Chemistry, Blood Glucose
Monitoring System

Nantong Egens Biotechnology Co., Ltd.
Building 9, Building 10, No.1692, Xinghu Avenue, Nantong
Economy & Technology Development Zone, 226010 Nantong,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Warehousing

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

Product Service

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