



Product Service

# CERTIFICATE

No. Q1N 16 05 63367 015

**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

**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

**Certification Mark:****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**

**Applied  
Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

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.:** SH1624111**Valid from:** 2016-09-01**Valid until:** 2019-08-31**Date,** 2016-08-16

Stefan Preiß



Page 1 of 1