



## DECLARATION OF CONFORMITY

**MANUFACTURER** Nantong Egens Biotechnology Co.,Ltd  
Building 15, Building 12( west) , No. 1692 Xinghu Avenue, Nantong  
Economy&Technology Development Zone, 226010 Nantong,  
People's Reepublic of China

**EUROPEAN REPRESENTATIVE** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany

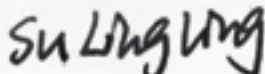
**PRODUCT** COVID-19 IgG/IgM Rapid Test Kit

**Model** Strip, Cassette

**CLASSIFICATION** Other

**CONFORMITY ASSESSMENT ROUTE** Annex III

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards, under our solo responsibility. All supporting documentations are retained under the premises of the manufacturer.

**Signature:** 

**Name:** Su Lingling

**Position:** Management Representative

General Manager

CE

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE ◆ CERTIFICATE



Product Service

# Certificate

No. Q5 063367 0018 Rev. 01

**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:**



**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). See also notes overleaf.

**Report No.:** TAM/SH1924115

**Valid from:** 2019-09-01  
**Valid until:** 2022-08-31

**Date,** 2019-07-31

Stefan Preiß  
Head of Certification/Notified Body

EGENS





# Certificate

No. Q5 063367 0018 Rev. 01

**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

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

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