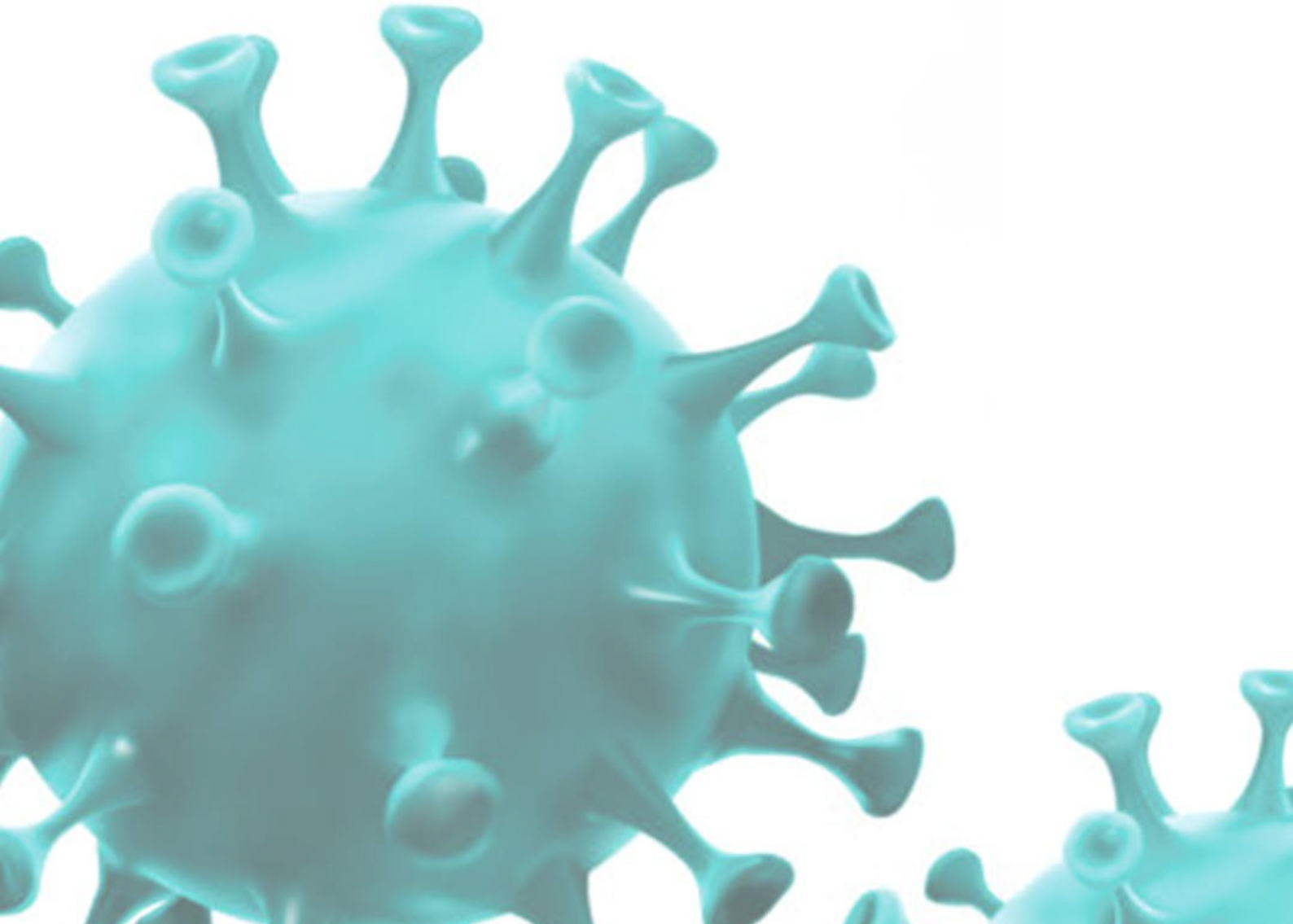
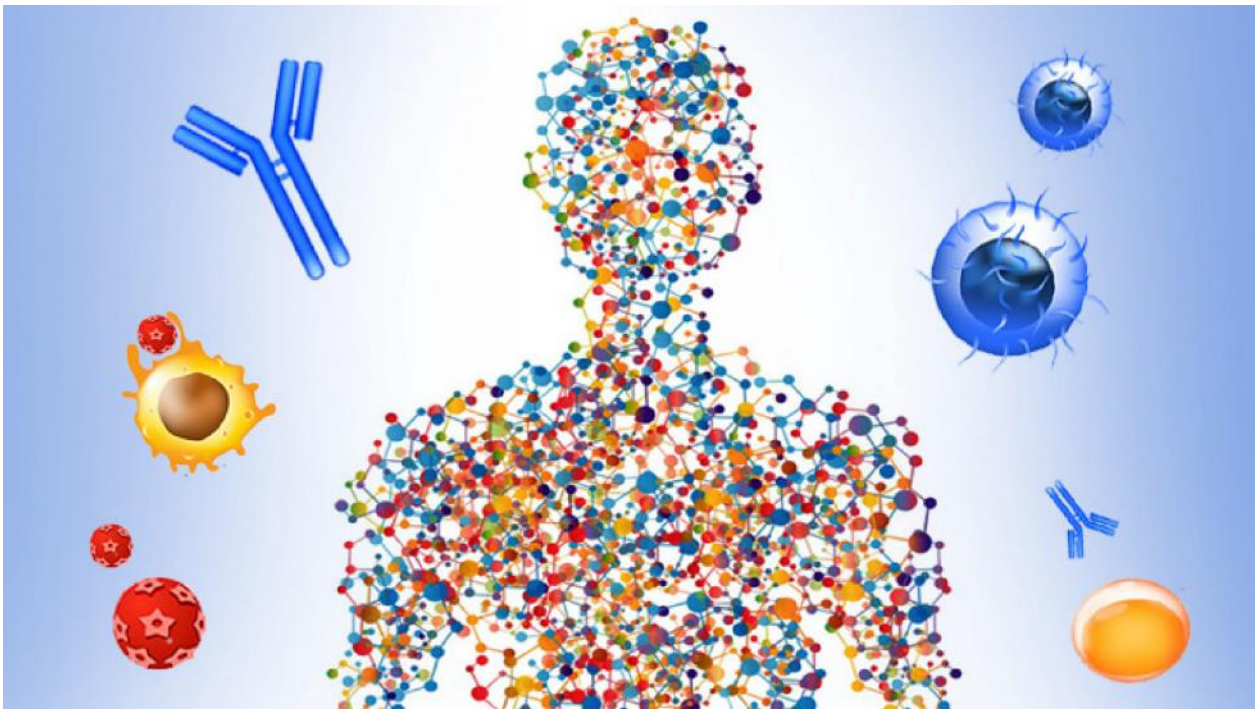
COVID-19 IgM/IgG Rapid Test Kit

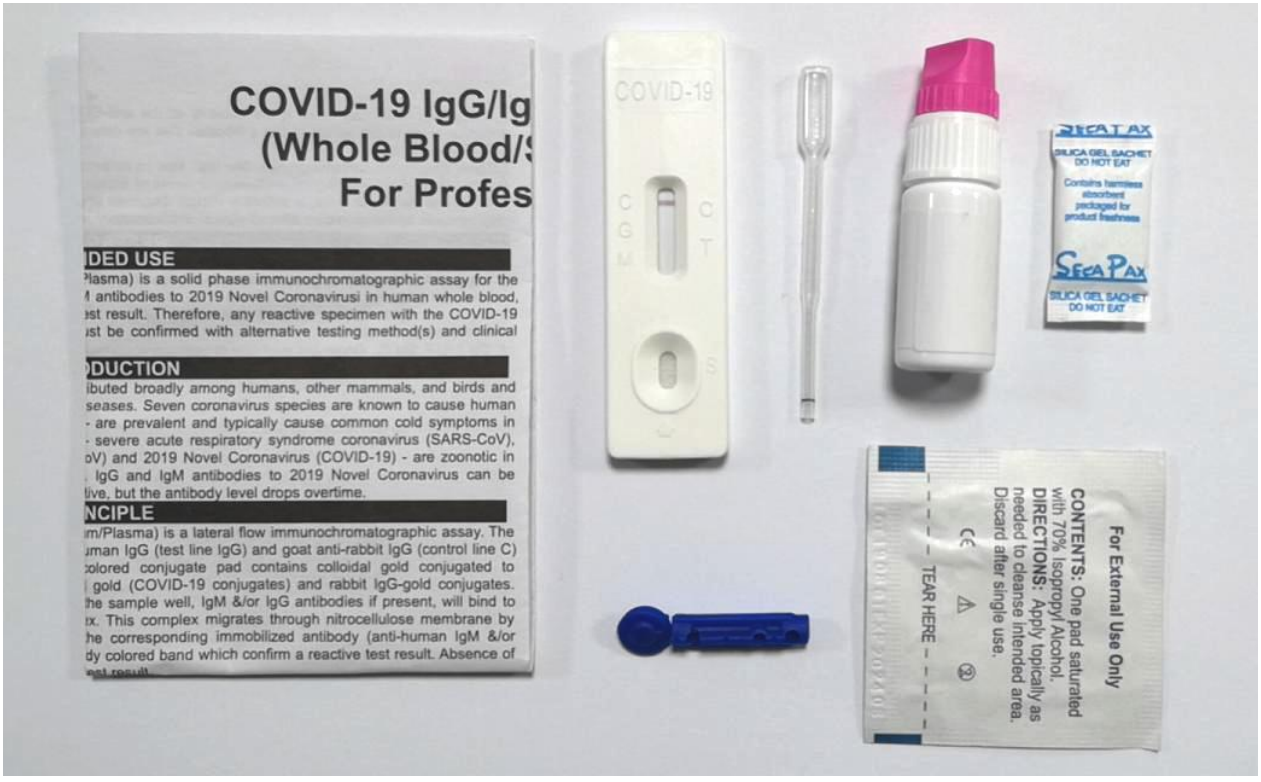
(Colloidal Gold)



PRODUCT

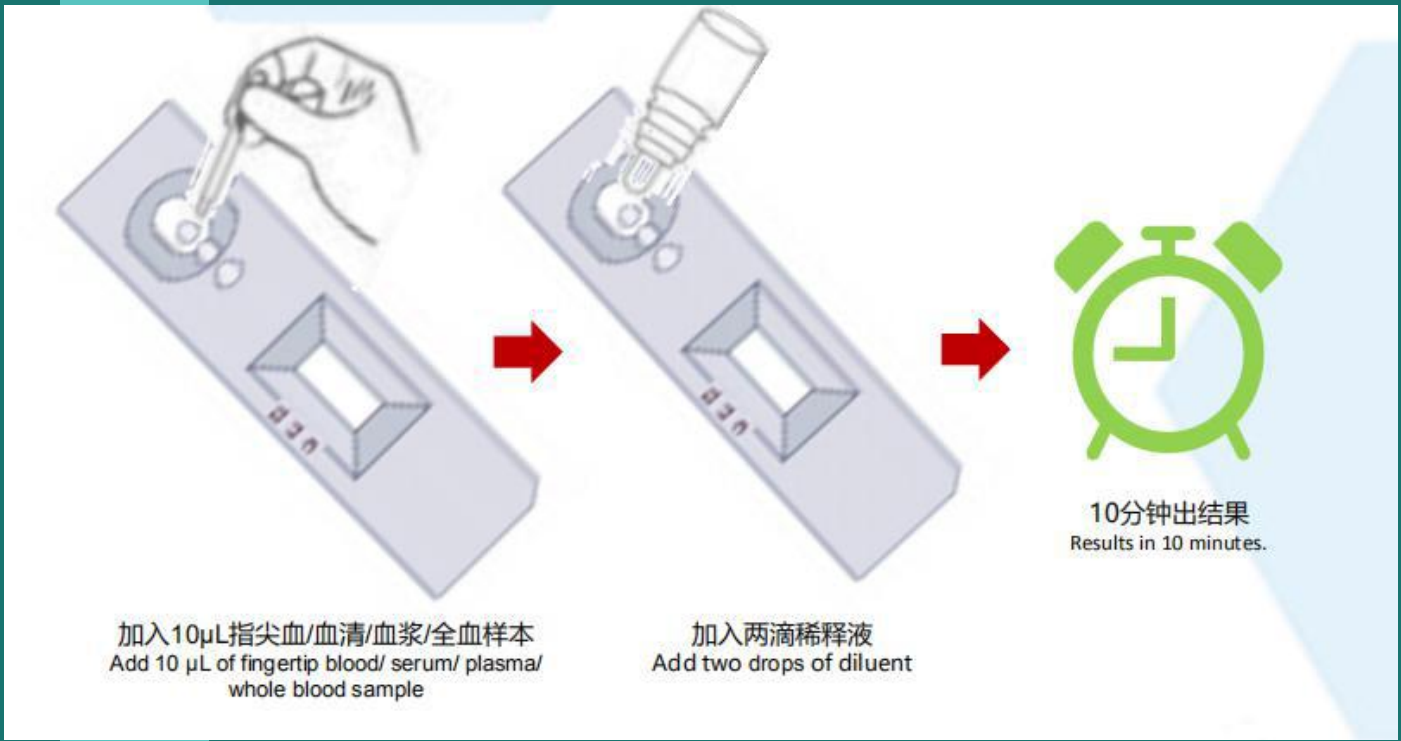


COVID-19 IgM/IgG Rapid Test Kit



OPERATING PROCEDURE

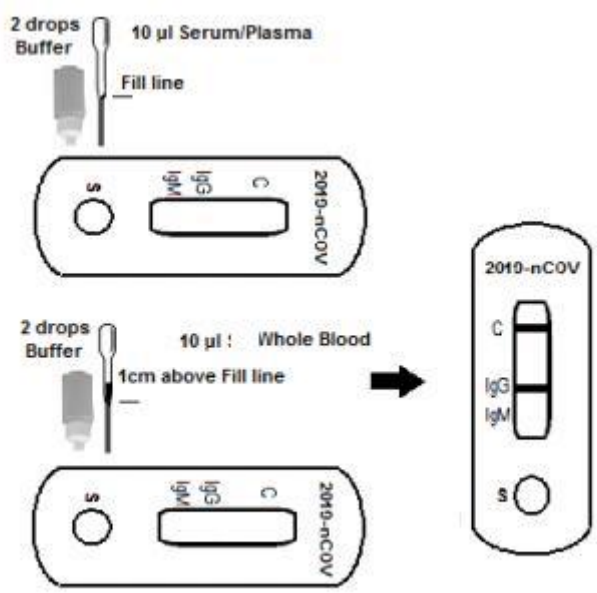
- The test card is restored to room temperature.
- 10μl sample of fingertip blood, whole blood, serum, plasma and two drops diluent were added to that loading well.
- 15 minutes, read the results.



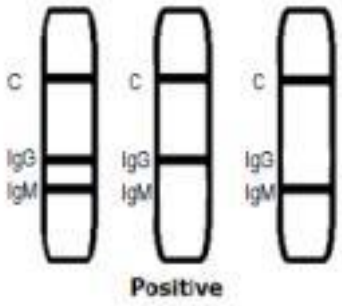
SCREENING FOR CORONA VIRUS IN 15 MINUTES

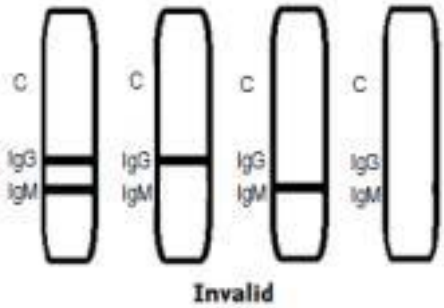
SIMPLE, PORTABLE AND FAST

- Fingertip blood collection
- Visual interpretation results
- Rapid detection
- Community Screening



Interpretation of Results:





COVID-19 PRODUCTS

IgG/IgM Rapid Test Kit

Principle	Indirect Method
Sample Type	Serum
Sample Volume	10 μL
Assay Incubation	80 minutes, RT
Total Wash Steps	2
Limit of Detection	5IU/mL
Repeatability	CV < 15%
Reproducibility	CV < 20%

Declaration of Conformity

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 Republic of China
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	**COVID-19 IgG/IgM Rapid Test Kit**
Model:	Strip, Cassette

Classification (IVDD, Annex II): Others

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 98/79/EC and Standards EN ISO13485:2016, under our sole responsibility.
All supporting documentations are retained under the premises of the manufacturer.

Signature: Su Lingling

Name: Su Lingling

Position: Management Representative

Date: 13-March-2020

Nantong Egens Biotechnology Co.,Ltd

CE

EC Declaration of Conformity
EGENS/CE-01, A/1

Acknowledgment Letter

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

3/26/2020

Joe Shia, Director
LSI International, Inc.
504 E. Diamond Ave, Suite #J
Gaithersburg, MD 20877
UNITED STATES

Dear Joe Shia:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EGENS EGENS EGENS
Received: 3/26/2020
Applicant: NANTONG EGENS Biotech Co., Ltd.
Device: EGENS COVID-19 IgG/IgM Rapid Test Cassette

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

CERTIFICATION FOR
Sale Transport of Chemical Goods

空 运
By Air

NO.2020151136

CNAS 中国认可 检验 INSPECTION CNAS I0071

货物运输条件鉴定书

Certification for Safe Transport of Chemical Goods

非限制性货物

样品名称： 新冠状病毒（2019-NCOV）IgG/IgM抗体联合检测试剂盒（胶体金法）

Sample Name: COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

委托单位： 南通伊仕生物技术股份有限公司

生产单位： 南通伊仕生物技术股份有限公司

上海化工院检测有限公司 检验检测专用章

上化院 上海化工院检测有限公司

Shanghai Research Institute of Chemical Industry Testing Co., Ltd

空 运
By Air

空 运
By Air

BUSINESS LICENSE

编 号 320600000201707100159

营 业 执 照

（副 本）

统一社会信用代码 91320600718557959C （1/1）

名　　称	南通伊仕生物技术股份有限公司
类　　型	股份有限公司(非上市)
住　　所	南通开发区星湖大道1692号15号厂房A座
法定代表人	欧卫军
注册资本	5781.3334万元整
成立日期	1999年12月07日
营业期限	1999年12月07日至******
经营范围	三类6840体外诊断试剂、二类6840临床检验分析仪器的生产（凭有效许可证）；生物技术研究、转让；电子仪器的组装、生产、销售；自营和代理各类商品和技术的进出口业务，但国家限定公司经营或禁止进出口的商品和技术除外。（依法须经批准的项目，经相关部门批准后方可开展经营活动）

登记机关 南通市工商行政管理局

2017 年 07 月 10 日

请于每年1月1日至6月30日履行年报公示义务

企业信用信息公示系统网址：www.jsgsj.gov.cn:58888/province

中华人民共和国国家工商行政管理总局监制

IVDD Instruction

Certificate of Holder

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

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

TÜV SÜD
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

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany NTYS-Y-1

Certificate of Holder

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

TÜV SÜD
Product Service

Certificate

No. Q5 063367 0018 Rev. 01

EGENS

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

仅供相关方信息登记使用

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

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany NTYS-Y-1

EUR Agreement

欧代协议（EUR Agreement）

Party A: Nantong Egens Biotechnology Co., Ltd.
Add: Building 15, Building12(West), No.1692, Xinghu Avenue,
Nantong Economy &Technology Development Zone,
Jiangsu Province 226010, P. R. China
Tel: +86- 513-85920700-8002 **Fax: +86- 513-85328020**
http:www. www.egens-bio.cn **E-mail: sue@egens-bio.cn**
甲方：南通伊仕生物技术股份有限公司
地址：中国江苏南通经济技术开发区星湖大道 1692 号 15 号厂房
电话：**+86-513-85920700-8002** 传真：**+86-513-85328020**

Party B: Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Ge
Tel: +
Dimdi No.:DE/00
乙方：上
地址：
电话：**+49**

甲乙双方在编号为 M/A2016-042 的欧盟代表协议项下约定的产品基础上，甲方需要新增如下 1 个产品：
COVID-19 IgG/IgM Rapid Test Kit (IVD Others)

经甲、乙双方商定，针对以上新增的产品，甲方给付乙方人民币
上述产品之授权代表期限从 2020 年 3 月 13 日起至 2022 年 8 月 13 日止，与原协议有效期一致。原协议条款内容仍然继续有效。除原协议及本补充协议外甲、乙双方不赋予其他权利和义务。

Party A: Nantong Egens Biotechnology Co., Ltd.
甲方：南通伊仕生物技术股份有限公司

(Signature and date)
(签字及日期) 2020.3.17

Party B:
乙方：上

(Signature and date)
(签字及日期) 2020.3.13.

GmbH (Europe)
Eiffestrasse 80
20537 Hamburg

Registration in Germany

(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00154142

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code DE/CA05		
	Bezeichnung / Name Behörde für Gesundheit und Verbraucherschutz, Referat V43		
	Staat / State Deutschland		Land / Federal state Hamburg
	Ort / City Hamburg		Postleitzahl / Postal code 20539
	Straße, Haus-Nr. / Street, house no. Billstraße 80		
	Telefon / Phone +49-40-428280		Telefax / Fax +49-40-427310017
	E-Mail / E-mail medizinprodukte@bgv.hamburg.de		

Anzeige / Notification		
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority	
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal	
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn	
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	

Cleaning 24 S.L
San Jaime 49, 1er Piso, 07840 Santa Eulalia del Rio - IBIZA

info@covid19-kit.es
José Luis Bousoño Rodríguez - Mobile +34 660761370
Jordan Assassa - Mobile +44 7818 565 879