Letter of Statement

Recently, there're foreign media reporting that the rapid test kits purchased from China by the Spanish Ministry of Health are not qualified. Reports said that these products came from Bioeasy. After informed of the news, our company attaches great importance to it and contacted the Spanish Ministry of Health. We learned that the product is currently in the verification stage and has not yet been put into use. We have also checked the production quality system as soon as possible, and carried out product verification and traceability for retained samples.

The Spanish Ministry of Health issued the latest statement on the evening of March 26, local time in Spain: The supplier of the rapid test kit has a legal EU CE certification, so it can be legally sold in Spain. (Annex I)

At present (March 26th local time in Spain), SEIMC is re-validating another antigen test products in accordance with the operating guidelines provided by our company. A formal verification report will be issued within 1-2 days, and our company will announce it as soon as we receive the formal verification report. Due to the severe epidemic situation in Spain and the time is urgent, the Spanish Ministry of Health, after consulting with our company and combining the verification data of March 26th local time, decided to replace another antigen test products and continue to perform the cooperation with Bioeasy, and required us to deliver relevant products on time to ensure the timely supply of Spanish anti-epidemic materials. Due to the rapid outbreak of epidemics in foreign country, European countries and other regions have not formed a unified, standard procedure for the use and method of COVID-19 rapid test products. The test results will be affected by various factors such as the patient's disease course, sampling location, and sampling accuracy. If there is less virus load in the specimen, the detection performance of some kits is not ideal, and false negative results may be produced.

Therefore, the occurrence of the foregoing matters does not rule out the possibility of deviations in results due to operational procedures during verification, patient records, sampling, etc. The specific reasons are still being communicated and verified by both parties. Our company attaches great importance to it, and deeply realizes that our company has not repeatedly communicated with customers about the details of the operation in the early stage of verification. Our company has instructed internal staff to make relevant product operation videos and more detailed operation instruction cards, and clarify with customers that product verification must be strictly performed in accordance with the above requirements.

Our company has been committed to exploring the international market and strictly obeying international laws and regulations to sell products. On March 12, 2020, we officially obtained the EU CE certification of four products of COVID-19. (Annex II & III)

If there is any latest progress in this incident, our company will announce it to the society in time.

Thank you very much!

Shenzhen Bioeasy Biotechnology Co.,Ltd.
Mar. 27th, 2020

www.bioeasy.com
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Annex I: Spanish Ministry of Health Statement

Prensa

GABINETE DE PRENSA

- Agenda de actos
- **Notas de prensa**
- Campañas informativas
- Fotografías
- Podcast
- Contacto del Gabinete de Prensa
- Información de la COP25

Notas de Prensa

La partida devuelta de test rápidos defectuosos contaba con homologación europea para su compra y comercialización en todo el espacio comunitario

- El Gobierno no adquirió estos test a China, sino a un proveedor nacional
- Esta operación, que no está relacionada con la compra de material sanitario anunciada ayer por el ministro Salvador Illa, se inició antes de que las autoridades chinas facilitaran nuevos listados de sus proveedores al Gobierno de España

26 de marzo de 2020.- Ante las informaciones aparecidas sobre la calidad de los test rápidos, es necesario aclarar que el Gobierno, a través del Ministerio de Sanidad, inició hace varias semanas los contactos con varias empresas para la adquisición de test diagnósticos, de los cuales existen varios sistemas en el mercado. El Gobierno adquirió una partida a un proveedor nacional, que los importaba de China y cuyo producto cuenta con el marcado CE. España se guía por la normativa de la UE y, por tanto, si un producto cuenta con la homologación europea, se puede comercializar y comprar en todo el espacio comunitario.

Además, por parte del Instituto de Salud Carlos III (ISCIII) se analizó la documentación aportada por la empresa respecto a los estudios clínicos realizados por el fabricante chino. También se comprobó que no existía ninguna alerta de la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) sobre este producto. Las primeras pruebas del test rápido se realizaron en paralelo en un hospital de Madrid y en el ISCIII y en cuanto se detectó una escasa sensibilidad, se dio orden inmediata de retirada; y se contactó con el proveedor que lo va a sustituir por otro tipo de test.

Esta operación, que no está relacionada con la compra de material sanitario anunciada ayer por el ministro Salvador Illa, se inició antes de que las autoridades chinas facilitaran nuevos listados de sus proveedores al Gobierno de España. No obstante, esos listados incluyen fabricantes validados y preferentes. En ningún caso consta información sobre la empresa china que, según la embajada, no cuenta todavía con la licencia correspondiente en China. Por parte del Ministerio de Sanidad sí se hicieron comprobaciones sobre la fiabilidad del proveedor nacional.

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Annex II: Bioeasy CE approval

qarad
European Regulatory Services

DECLARATION OF NOTIFICATION

Date: March 17, 2020

The undersigned, Teresa Batet i Solà, Senior Consultant, of Qarad EC-REP BV, hereby declares that:

Shenzhen Bioeasy Biotechnology Co., Ltd.

No. 2-1, Liuxian 1st Road, Xin'an Sub-District, Baoan District,
Shenzhen, Guangdong Province, China. 518101

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Name Device	Catalogue number Device
BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test	YRLG22201025, YRLG22201050, YRLG22201100
BIOEASY™ Diagnostic Kit for 2019-Novel Coronavirus (2019-nCoV) Ag Test Kit (Fluorescence Immunochromatographic Assay)	YRLF04401025, YRLF04401050, YRLF04401100
BIOEASY™2019-Novel Coronavirus (2019-nCoV) IgG/IgM GICA Rapid Test (Colloidal Gold):	YRLG22301025, YRLG22301050, YRLG22301100
BIOEASY™ 2019-Novel Coronavirus (2019-nCoV) Ab GICA Rapid Test	YRLG22501025, YRLG22501050, YRLG22501100

The notification to the Belgian Competent Authorities has been carried out on March 12th, 2020 by Qarad EC-REP BV, the appointed Authorized Representative of Shenzhen Bioeasy Biotechnology Co., Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Teresa Batet i Solà
Senior Consultant

Qarad EC-REP BV
Authorized Representative

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Tel. +32 (0)14 49 04 22 | ECREP@qarad.com | www.qarad.com

Annex III: Bioeasy ISO13485

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

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

Product Service

Certificate

No. Q5 102038 0001 Rev. 00

Holder of Certificate: **Shenzhen Bioeasy Biotechnology Co., Ltd.**
No.11 R&D Center
Taohuayuan Science & Technology Innovation Park
Xixiang Street, Baoan District
518102 Shenzhen, Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of IVD Reagent and Analyzer of Immunochromatographic method**

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.: GZ1839001

Valid from: 2019-07-12
Valid until: 2022-07-11

Date, 2019-07-12

Stefan Preiß
Head of Certification/Notified Body

A4 / 07.17

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

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