



浙江东方基因生物制品股份有限公司

Zhejiang Orient Gene Biotech Co.,LTD

Announcement for New Export Requirement from China's Minister of
Commerce on COVID-19 Testing kit Product

Zhejiang Orient Gene Biotech Co., Ltd.

Dear valued customers and business partners of Zhejiang Orient Gene Biotech,

This is to inform all the related parties of the company that China's Minister of Commerce published a new announcement at 10 pm, 2020/3/31, Beijing Time. Starting on April 1st, 2020, all companies who export coronavirus-related medical devices including testing kits, medical masks, protective gears, ventilators and all other PPEs, are required to provide a written or electronic version of declaration indicating that the product possesses China's Medical Device Product Registration Certificate as well as meets the quality standard requirement in the importing countries when declaring customs in China.

Since more than 95% of sales of Zhejiang Orient Gene Biotech (hereinafter called the 'ZOGB') are from overseas market, ZOGB invested large amount of resources and efforts in acquiring relevant certificates for the testing kit products in the international market starting early February. Up to now, ZOGB acquired permission to sell both COVID-19 IgG-IgM Test Cassette and 2019-nCoV Detection Kit (Fluorescence PCR) in several major international markets including European Union and United States. Due to the priority of company's business strategy in mainland China where less than 5% of sales is generated, ZOGB is still in the process of acquiring China's Medical Device Product Registration Certificate, which is solely used as a permission to sell medical device products in China's market. When informed of the sudden update in export requirement, the senior management team of ZOGB immediately arranged top-level conference at midnight on April 1st, 2020.

For the purpose of best supplying products to the company's overseas clients, ZOGB is actively cooperating with the regulators and governments in China to develop feasible solutions at this moment, including utilizing various resources and supports to expedite the application process of China's Medical Device Product Registration Certificate. The expected date to acquire certain registration certificate is targeted sometime next week. Besides, ZOGB also established a Plan B to secure a on-time delivery of all the testing kit products by leveraging its solely-owned US Affiliate Healgen Scientific LLC. As such, ZOGB is confident in continuing

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provide the best quality products and services for all clients and business partners.

The sudden release of new export requirement from China's Minister of Commerce was primarily due to the incident of Spain returns faulty COVID-19 test kits to China earlier this week. The Spanish government bought a batch of faulty COVID-19 testing kits from an unauthorized Chinese company called Shenzhen Bioeasy Biotechnology, who is an uncertified company with no required license from Chinese National Medical Products Administration, resulted in a 9,000 test kits failed to meet specification in Spain. In contrast, ZOGB has collaborated with Grade-A Tertiary Hospital, medical labs and Zhejiang Center for Disease Control and Prevention to conduct more than 1,000 clinical trials on the test kit products during the past two months, which indicate an efficacy up to 97% in detecting coronavirus. Besides, the tests of ZOGB's products conducted by major hospitals and testing agencies in Spain, Italy, Belgium, and more, also successfully rendered an excellent sensitivity of 93%.

As a public company listed on China's NASDAQ-like SSE STAR MARKET, ZOGB is one of the leading domestic POCT suppliers in mainland China. ZOGB owns an excellent track record of producing and providing the best-quality since its establishment in 2008, and obtains dozens of CFDA Product Certificates, FDA (510K) Product Certification, EU CE Product Certifications and Canada MDL Product Certifications, etc.

Under the current situation, ZOGB is dedicated to prevent the case of "Bad money drives out good" in the COVID-19 testing kit market. We are hopeful that with our efforts and cooperation with China's government and regulators, we will resolve this issue shortly. We strongly believe that we will overcome this global epidemic crisis and defeat the virus with our joint effort.

Regards,

Zhejiang Orient Gene Biotech

April 1st, 2020