Confirmation

of EU product notifications submitting

Herewith we confirm that

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraase 80, 20537 Hamburg, Germany

has taken over the function of an European Authorised Representative according to the requirements of IVD Directive 98/79/EC for:

Zhejiang Orient Gene Biotech Co., Ltd
3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China

for their in-vitro diagnostic device:
1) Coronavirus Ag Rapid Test Cassette (Swab)
2) COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
3) SARS-CoV-2 Detection Kit (Fluorescence PCR)

and has submitted the product notifications at the relevant German Competent Authority according to Article 10(3) of the above mentioned IVD Directive and all supporting technical documents are deposited in our office. The product notifications are estimated to be completed within 3 months.

14 February 2020

Shanghai International Holding Corporation GmbH (Europe) Eiffestrasse 80 20537 Hamburg

Mr. Jin Liang
-- on behalf of --
Shanghai International Holding Corp. GmbH (Europe)