

WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs PUBLIC REPORT

Product: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)

EUL Number: EUL 0588-238-00

Outcome: Not Recommended.

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents;
- Product Dossier Review: assessment of the documentary evidence of safety and performance.

Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) with product code K511416D, manufactured by Hangzhou Realy Tech Co., Ltd, Building #2, No.763, Yuansha Village Xinjie Street, Xiaoshan District Hangzhou City, Zhejiang Province, China, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Hangzhou Realy Tech Co., Ltd was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff and external technical experts (assessors), it was established that insufficient information was provided by Hangzhou Realy Tech Co., Ltd. to fulfil the requirements described in the *"Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen, PQDx_347"*.