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

Product: SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)
EUL Number: EUL 0612-246-00
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:


SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) with product code LFA0401-25N, manufactured by Shenzhen Watmind Medical Co., Ltd, 8th Floor, Building A, No.16 -1 Jinhui Road, Jinsha Community Kengzi subdistrict, Pingshan District 518118, Shenzhen, China, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Shenzhen Watmind Medical 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 Shenzhen Watmind Medical 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 ”.