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

Product: LightPower iVASARS-CoV-2 1stRT-rPCR Kit
EUL Number: EUL 0524-210-00
Outcome: Not Accepted.

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.

LightPower iVASARS-CoV-2 1stRT-rPCR Kit with product code VA.A02-055H, manufactured by Viet A Technology corporation, 372A/8 Ho Van Hue, Ward 9, Phu Nhuan District, Ho Chi Minh City, Vietnam, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Viet A Technology corporation was asked to provide up-to-date information about the status of their quality management system.

Upon review of the submitted documentation by Viet A Technology corporation in support of a desk assessment on the Quality Management System of the manufacturer, the information submitted did not constitute adequate evidence of compliance with ISO 13485: 2016 Medical devices - Quality management systems - Requirements for regulatory purposes and the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347".*