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

Product: StrongStep Novel Coronavirus (SARS-CoV-2) Multiplex Real Time PCR Kit (detection for three genes)
EUL Number: EUL 0519-206-00
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.

StrongStep Novel Coronavirus (SARS-CoV-2) Multiplex Real Time PCR Kit (detection for three genes) with product code 500190, manufactured by Liming Bio-Products Co., Ltd., No.12, Huayuan Road, Nanjing, Jiangsu 210042, China, is not eligible for WHO procurement.

Product dossier assessment

Liming Bio-Products Co., Ltd. was requested to submit a product dossier for StrongStep Novel Coronavirus (SARS-CoV-2) Multiplex Real Time PCR Kit (detection for three genes) as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_0347)"*. Liming Bio-Products CO., Ltd did not submit the requested information (data and documentation). Therefore, the assessment was closed as there was no evidence of compliance of the documentary evidence of safety and performance as described in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347*."