WHO Emergency Use Assessment SARS-CoV-2 IVDs
PUBLIC REPORT

Product: OHC COVID-19 Antigen Self-Test
Manufacturer: OSANG Healthcare Co., Ltd
EUL Number: EUL 0698-08810-00
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.

OHC COVID-19 Antigen Self-Test with product codes OI-01SA-SH manufactured by OSANG Healthcare Co., Ltd, located at 132 Anyangcheondong-ro Dongan-gu, Anyang-si Gyeonggi-do, 14040, Republic of Korea, is not eligible for WHO procurement.

Quality Management Systems Review

To establish eligibility for WHO procurement, OSANG Healthcare Co., Ltd was asked to provide up-to-date information about the status of its 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 OSANG Healthcare Co., Ltd provided insufficient information 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."*