World Health Organization

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In reply, please refer to: CC/sh

Your reference: P17-370-9

Premier Medical Corporation Private Limited
Attention: Dr Rajeshkumar G. Sheliya
Director
A1-302, GIDC
Sarigam, District, Valsad
396155
Inde

11 November 2022

Dear Dr Sheliya,

Subject: WHO Emergency Use Assessment and Listing (EUL) – Amended Final Public Report

Product Name: Sure Status COVID-19 Antigen Card Test
Application Number: EUL 0590-010-00
Product Code: SS03P25 and SS03-NS-P25
Regulatory version: RoW

We are pleased to inform you that the EUL public report for the above-referenced product was amended on 8 November 2022. The amendment was due to introduction of a new product code SS03-NS-P25 that uses nasal swab specimen type and changes to the sample pad to filter the sticky part of the nasal discharge.

Please be advised that the ongoing eligibility status of the above-referenced product depends on fulfilling the following commitments concerning issues identified during the WHO EUL procedure.

1. Participate in the WHO collaborative study to assess the suitability of an interim standard for SARS-CoV-2 virus antigen detection tests.
2. To submit a study report on estimating the analytical sensitivity with the WHO International Standard when it becomes available.
3. When this becomes available, submit a study report on the traceability of all relevant materials to the International SARS-CoV-2 virus standard.
4. To submit interim and final stability reports by 30 June 2023.

ENCL: as stated

The following activities are required to maintain the eligibility status:

1. Notification to WHO of any planned changes to the above-referenced product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic*" (document number PQDx_121); and

2. Post-market surveillance activities, in accordance with "Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics" (ISBN 978-92-4-001531-9).

Failure to comply with any of the requirements mentioned above may lead to remedial action by WHO, including but not limited to de-listing from the WHO EUL procedure list of eligible in vitro diagnostics products.

If you have any questions, please do not hesitate to contact us by email (diagnostics@who.int) or by telephone (+41 22 791 3927).

Yours sincerely,

p.p. 

Mr Deus Mubangizi
Unit Head
Prequalification Unit
Regulation and Prequalification Department
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