World Health Organization

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In reply please refer to: CC/vl

Your reference: P17-370-9

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

13 January 2021

Dear Dr Sheliya,

Subject: WHO Prequalification of In Vitro Diagnostics – Final Public Report

Product name: First Response Syphilis Anti-TP Card Test
Product codes: PI08FRC25, PI08FRC50 and PI08FRC100
Regulatory version: Rest of World
Manufacturer: Premier Medical Corporation Private Limited
PQDx Reference Number: PQDx 0471-010-00

We are pleased to inform you that the above-referenced product was prequalified on 13 January 2021 and listed on the World Health Organization (WHO) list of prequalified in vitro diagnostic products.

The following post-prequalification activities are required to maintain the prequalification status:

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

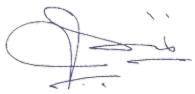
2. Post-market surveillance activities, in accordance with "WHO guidance on post-market surveillance of in vitro diagnostics" (ISBN 978 92 4 150921 3).

You are also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents. The sales data will serve as denominator data to guide the frequency of re-inspection.

Failure to comply with any of the above-mentioned post-prequalification requirements may lead to remedial action by WHO, including but not limited to, de-listing from the WHO list of prequalified in vitro diagnostic products.

If you have any questions, please do not hesitate to contact us by email (diagnostics@who.int) or by telephone (+4122 791 3927).

Yours sincerely,



Mr Deus Mubangizi
Unit Head
Prequalification Unit
Regulation and Prequalification Department