World Health Organization

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In reply, please refer to: CC/df

Your reference: P17-370-9

Premier Medical Corporation Private Limited
Attention: Dr Rajeshkumar G. Sheilya
Director
A1-302/ GIDC
Sarigam, Dist., Valsad
396 155
Inde

28 September 2023

Dear Dr Rajeshkumar G. Sheilya,

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

Product name: First Response Syphilis Anti-TP Card Test
Product codes: PI08FRC25, PI08FRC50, PI08FRC100, and PI08FRC25-SA
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 prequalification public report for the above-referenced product was amended on 22 September 2023. The public report was amended due to the introduction of the new pack size with auto safety lancet, PI08FRC25-SA, in addition to the existing prequalified catalogues of PI08FRC25, PI08FRC50, and PI08FRC100.

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

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.

ENCL: as stated

Failure to comply with any of the above-mentioned post-prequalification requirements may lead to remedial action by the 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 telephone (+4122 791 3927).

Yours sincerely,

Mr Deus Mubangizi
Unit Head
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division