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 Patel
Department of General Management
1304 Johnston Drive
Watchung, New Jersey
07069
Etats-Unis d'Amérique

12 March 2020

Dear Dr Patel,

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

Product name: First Response HIV 1-2.O Card test (Version 2.0)
Product codes: PI05FRC25, PI05FRC30, PI05FRC50, PI05FRC60 and PI05FRC100
Regulatory version: Rest of World
Manufacturer: Premier Medical Corporation Private Limited
PQDx Reference Number: PQDx 0363-010-00

We are pleased to inform you that the prequalification public report for the above-referenced product was amended on 12 March 2020. The amendment was due the following accepted change notification,

"*1. Addition of two new bulk packs added, as 5 test pack and 10 test packs.*
2. Replacement of twist lancet with Auto safety lancet for the catalogue no. P105FRC60.
3. A new specimen transfer device having "10 µl & 20 µl marking line" was introduced to make it more user friendly. This involved a change to components and to labelling for the existing and new pack sizes."

ENCL: as stated

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 5891).

Yours sincerely,

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