World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 3927
Fax direct: +41 22 791 4836
E-mail : diagnostics@who.int

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' Amerique

24 June 2019

Dear Dr Patel,

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

**Product name:** First Response® HIV 1+2/Syphilis Combo Card Test
**Product codes:** I20FRC25, I20FRC30, I20FRC50, I20FRC60 and I20FRC100
**Regulatory version:** Rest of World
**Manufacturer:** Premier Medical Corporation Private Limited
**PQDx Reference Number:** PQDx 0364-010-00

We are pleased to inform you that the above-referenced product was prequalified on 24 June 2019 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).

ENCL: as stated

Digitally signed by Chirtoacă Iurie
Date: 2022.10.28 17:19:11 EEST
Reason: MoldSign Signature
Location: Moldova

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
Coordinator
Prequalification Team
Regulation of Medicines and other Health Technologies