



Tel. direct: +41 22 791 2801
Fax direct: +41 22 791 4836
E-mail: diagnostics@who.int

In reply, please
refer to: CC/sh

Your reference: P17-370-9

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

20 November 2023

Dear Dr Sheliya,

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

Product name: First Response HCV Card Test
Product codes: PI03FRC25, PI03FRC50 and PI03FRC100.
Regulatory version: Rest-of-World
Manufacturer: Premier Medical Corporation Private Limited
PQDx Reference Number: PQDx 0469-010-00

We are pleased to inform you that the above-referenced product was prequalified on 13 November 2023 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 “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 re-inspection frequency.

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.

ENCL: (as stated)

If you have any questions, please do not hesitate to contact us by e-mail (diagnostics@who.int) or telephone (+4122 791 2801).

Yours sincerely,

p.p.



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