CERTIFICATE

EC Certificate No. 1434-IVDD-394/2020

Full Quality Assurance System

Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Premier Medical Corporation Private Limited

A1-302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, INDIA

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

First Response® HBsAg Card Test

Ref: PI10FRC05CE, PI10FRC10CE, PI10FRC25CE, PI10FRC30CE

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 26.10.2020 to 27.05.2024

The date of issue of the Certificate: 26.10.2020

CE 1434

Digitally signed by Matei Andrei
Date: 2022.06.06 13:38:22 EEST
Reason: MoldSign Signature
Location: Moldova

Issued under the Contract No. **MD-121/2019**
Application No: 185/2017
Certificate bears the qualified signature.
Warsaw, 26.10.2020
Module H7

Anna Małgorzata Wyroba
Vice-President

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.26 10:59:54 +01'00'

CERTIFICATE

EC Certificate No. 1434-IVDD-396/2020

Full Quality Assurance System

Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Premier Medical Corporation Private Limited

A1-302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, INDIA

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

First Response® HCV Card Test

Ref: PI03FRC05CE, PI03FRC10CE, PI03FRC25CE, PI03FRC30CE

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 26.10.2020 to 27.05.2024

The date of issue of the Certificate: 26.10.2020

CE 1434

Issued under the Contract No. **MD-121/2019**
Application No: 186/2017
Certificate bears the qualified signature.
Warsaw, 29.09.2020
Module H7

Anna Małgorzata Wyroba
Vice-President

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.26 11:10:39 +01'00'

सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2018/000064

Endorsement No. 1

1. M/s PREMIER MEDICAL CORPORATION PRIVATE LIMITED, A1-302 GIDC Sarigam Dist, Valsad, Gujarat (India) - 396155 Telephone No.: 260 2780112, 260 2780113 FAX: 260 2242411 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PREMIER MEDICAL CORPORATION PRIVATE LIMITED, A1-302, GIDC, Sarigam , Valsad, Gujarat (India) - 396155 Telephone No.: 260-2780112, 260-2780113 FAX: 260-2242411

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION ., 2.5.4.20=cec9e6dd3ecf4caa36d3ae9e432d59a6f4c3a02cb467e76d5edcdb3a731ee144, ou=DGHS,CID - 6432120, postalCode=110002, st=Delhi, cn=S ESWARA REDDY
Date: 2019.07.15 16:53:04 +05'30'

1	Generic Name:HIV 1+2/ SYPHILIS Combo Card Test Model No.:I20FRC01 - 1 No. each (Test Device,1 Instructions for use - ,I20FRC10 - 10 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Sterile Single-use Lancets - ,Alcohol Swab) with 1 Assay buffer bottle - ,1 Instructions for use - ,I20FRC25 - 25 No. each(Test Device,Desiccant - , Specimen Transfer Device - ,Sterile Single-use Lancets - ,Alcohol Swab) with 1 Assay buffer bottle - , 1 Instructions for use - ,I20FRC30 - 30 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Sterile Single-use Lancets - ,Alcohol Swab) with 1 Assay buffer bottle - ,1 Instructions for use - , I20FRC50 - 50 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Sterile Single-use Lancets - ,Alcohol Swab) with 2 Assay buffer bottle - ,1 Instructions for use - ,I20FRC60 - 60 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Sterile Single-use Lancets - ,Alcohol Swab) with 4 Assay buffer bottle - ,1 Instructions for use - ,I20FRC100 - 100 No. each (Test Device, Desiccant - ,Specimen Transfer Device - ,Sterile Single-use Lancets - ,Alcohol Swab) with 4 Assay buffer bottle - ,2 Instructions for use - ,I20FRC05s - 5 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Assay Buffer Vial - ,Sterile Single-use Lancets - ,Alcohol Swab - ,Instructions for use) and master instruction for use - ,I20FRC10s - 10 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Assay Buffer Vial - ,Sterile Single-use Lancets - ,Alcohol Swab - ,Instructions for use) and master instruction for use - ,I20FRC25s - 25 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Assay Buffer Vial - ,Sterile Single-use Lancets - ,Alcohol Swab - ,Instructions for use) and master instruction for use - ,I20FRC30s - 30 No. each (Test Device,Desiccant - ,Specimen Transfer Device - ,Assay Buffer Vial - ,Sterile Single-use Lancets - ,Alcohol Swab - ,Instructions for use) and master instruction for use - ,Desiccant - ,Specimen Transfer Device - ,Assay Buffer Vial - ,Sterile Single-use Lancets - ,Alcohol Swab - ,Instructions for use) - ,I20FRC05 - 5 No. each (Test Device,Desiccant - , Specimen Transfer Device - ,Sterile Single-use Lancets - ,Alcohol Swab) with 1 Assay buffer bottle - Intended Use:First Response® HIV 1+2 / Syphilis Combo Card Test is intended for use by healthcare professionals and trained user. It is a rapid, qualitative screening, in vitro diagnostic test for the detection of antibodies (IgG & IgM) specific to HIV (type 1 & 2) and Treponema pallidum in human serum, plasma or whole blood. The test kit is not automated and does not require any additional instrument. Reactive specimens should be confirmed further with ELISA, Western Blot or TPHA. Class of medical device:Class D Material of construction:Plastic device assembles with nitrocellulose membrane coated with recombinant antigen Dimension(if any): Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):FIRST RESPONSE®

Place:

Date12-Jul-19

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION , 2.5.4.20=cec9e6dd3ecf4caa36d3ae9e432d59a6f4c3a02cb467e76d5edcdb3a731ee144, ou=DGHS,CID - 6432120, postalCode=110002, st=Delhi, cn=S ESWARA REDDY
Date: 2019.07.15 16:53:17 +05'30'

Central Licensing Authority

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Premier Medical Corporation Private Limited
A1-302, GIDC
Sarigam
Dist. Valsad 396 155
Gujarat
India

Holds Certificate No: **MD 584949**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The Design, Development and Manufacture of In-vitro Diagnostics Kits for Diagnosis of Infectious Diseases.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2006-02-20
Effective Date: 2021-02-21
Latest Revision Date: 2021-08-03
Expiry Date: 2024-02-20

...making excellence a habit.™

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

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

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 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

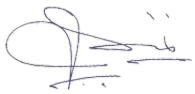
2. Post-market surveillance activities, in accordance with "WHO guidance on post-market surveillance of in vitro diagnostics" (ISBN 978 92 4 150921 3).

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

World Health Organization

WHO list of prequalified in vitro diagnostic products

RoW: Rest of the world. Regulatory version applied to products not approved by stringent/mature NRAs or not regulated

Last update: 22 February 2022

Year prequalified	Type of assay	Product name	Product code(s)	Regulatory version	Manufacturer	Manufacturing site(s)	Packaging
2019	HBsAg RDT	*Determine HBsAg 2	7D2942; 7D2943; 7D2943 SET	CE-mark	Alere Medical Co. Ltd	357 Matsuhidai, Matsudo-shi, 270-2214, Chiba-ken, Japan	20 T/kit 100 T/kit 100 T/kit
2019	HCV EIA	ARCHITECT HCV Ag assay	6L47-29; 6L47-11; 6L47-02; and 8C89-01	CE-mark	Denka Seiken Co., LTD, Kagamida Factory	Street 1359-1, Kagamida, Kigoshi, Gosen-shi, Niigata, Japan	100 T/kit
2019	HIV RDT for self-testing	*Mylan HIV Self Test	ARST001-03; ARST001-03-01; ARST001-03-02; ARST001-03-03	RoW	Atomo Diagnostics Pvty. Ltd	**Site 1:** Atomo Diagnostics Pty Ltd atLevel 2, 701-703 Parramatta Road, Leichardt 2040 NSW, Australia **Site 2**: Lateral Flow Laboratories (LFL) at Unit 1 & 2, Greenwich Place, Capricorn Crescent, Capricorn Technology Park, Muizenberg,7945, South Africa	1 T/kit; 1 T/kit; 1 T/kit; 1 T/kit.
2019	HIV/Syp RDT	*First Response HIV1+2/Syphilis Combo Card Test	I20FRC25; I20FRC30; I20FRC50; I20FRC60; I20FRC100	RoW	Premier Medical Corporation Private Limited	Sarigam, Gujarat, India	25 T/kit 30 T/kit 50 T/kit 60 T/kit 100 T/kit
2019	HIV RDT	*ONE STEP Anti-HIV (1&2) Test	ITPW02152-TC40; ITPW02152-TC25; ITPW02153-TC40 ITPW02153-TC40SA	RoW	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit 40 T/kit
2019	HCV RDT	Rapid Anti-HCV Test	ITPW01152-TC40; ITPW01152-TC25; ITPW01153-TC40	RoW	InTec PRODUCTS, INC	308, Wengjiao Rd, Xinyang IND. AREA, Haicang, Xiamen, 361022, China	40 T/kit 25 T/kit 40 T/kit
2019	Malaria RDT	AdvDx Malaria Pf Rapid Malaria Ag Detection Test	00-DKM-RK-MALADX-004-025	RoW	Advy Chemical Pvt Ltd.,	Plot No.A-334,336,338 & A-337 & 339 Road no. 25 & 26, Wagle industial Estate Thane 400 604 India	25 T/kit
2019	Malaria RDT	*NxTek Eliminate Malaria Pf	05FK140	CE-mark	Abbott Diagnostics Korea Inc	**site 1:** 46**,** Hagal-ro 15 beongil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea **site 2:** 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea	25T/Kit
			05FK141				25T/Kit
			05FK142				1T/kit x 25 each
			05FK143				1T/kit x 25 each
2019	HIV NAT	*m-PIMA HIV-1/2 VL	27015-W50	RoW	Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1, D-07743 Jena, Germany	50 cartridges/kit
		First Response Malaria Antigen P	PI13FRC25s			**site 1:** A1-302, GIDC, Sarigam 396 155, Valsad, Gujarat, India;	25 × single kit
			PI13FRC10s				10 × single kit