



Premier Medical Corporation Private Limited

Unit-I

32-35, Shree Ganesh Indl. Estate, Kachigam,
Nani Daman, Daman - 396 215, (U.T.) INDIA

Unit-II

A1-302, GIDC, Sarigam 396155. Dist. Valsad,
Gujarat, INDIA • Tel.: +91 260 2780112 / 113

Declaration of Conformity

Reference No: PMC/QA/22/006

Doc No.: DOC/I20FRC (Rev. AC)

Manufacturer Name:

Premier Medical Corporation Private Limited

Manufacturer Address:

Premier Medical Corporation Private Limited
A1-302, GIDC, Sarigam – 396155. Dist. Valsad, Gujarat, India

European Representative Name:

Obelis S.A.

European Representative Address:

Bd. General Wahis, 531030 Brussels, Belgium

Product Name:

First Response® HIV 1+2/Syphilis Combo Card Test

Catalogue No.:

I20FRC25, I20FRC30, I20FRC50, I20FRC60, I20FRC100

Conformity Assessment Route:

Full Quality Assurance (ISO & EN ISO 13485:2016) audit by;

Standard Applied:

ISO 13485:2016, EN ISO 18113-2:2011,
EN ISO 13485:2016, EN ISO 15223-1:2021,
EN ISO 14971:2012, EN ISO 23640:2015,
EN ISO 18113-1:2011, BS EN 13612:2002

Certified Body:

BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes
MK58PP. Tel.: +44 345 080 9000

Certificate No.

MD 584949

Valid Until: 2024-02-20

We herewith declare that the above-mentioned product is manufactured as per Quality Management System requirement according to ISO 13485:2016 and EN ISO 13485:2016. All supportive documentation is retained under the premises of the manufacturer.

On Behalf of Premier Medical Corporation Private Limited


2022-01-08
MEDICAL CORPORATION PVT. LTD. SARIGAM

Mr. Vikas Nakrani

General Manager - Quality Assurance & Regulatory Affairs

Place: Sarigam, Gujarat, India.