



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/IVD/2021/000068

Endorsement No. 5

- M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 4th Floor, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343
- Details of medical device(s) [Annexed]
- 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
- This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Malaria Pf Rapid Test Kit Model No.:PKRK008 - NA Intended Use:The Malaria Pf Rapid Test is a visual, rapid and sensitive solid phase immunochromatographic assay for the qualitative differential detection of P. falciparum (HRP-2) antigen in the blood sample. Class of medical device:Class C Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Malaria Pf Rapid Test Kit</p>

Place:

Date:10-May-22

VENUGOPAL G SOMANI
Central Licensing Authority
Digitally signed by VENUGOPAL G SOMANI
DN: cn=VENUGOPAL G SOMANI, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=CDSCO, postalCode=110002, st=DELHI, serialNumber=0724, hashObject=15222396a070291849226b2945c456d249073e
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