



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

1. 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, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

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)
1	<p>Generic Name:COVID-19 Ag Rapid Test Model No.:PKRK001 - NA Intended Use:The Simple COVID-19 Ag Rapid Test is a lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal and nasopharyngeal (NP) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. It is intended for the identification of infection with SARS-CoV-2, in the human body. 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):PathKits Simple COVID-19 Ag Rapid Kit</p>

Place:

Date 08-Jul-21

VENUGOPAL
GIRDHARILAL
SOMANI

Digitally signed by VENUGOPAL
GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS,
ou=CDS&CO DGHS, postalCode=431401,
st=Maharashtra,
2.5.4.20=173003345df62d489632379a1471
bf1de9f0b28e55c6c3b7b0e2154e39961a77,
cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.07.08 15:14:31 +05'30'

Central Licensing Authority