



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. 4

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:Influenza A/B Antigen Test Kit</p> <p>Model No.:NIL</p> <p>Intended Use:Influenza A/B Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of Influenza A and B antigens in nasal swab or Nasopharyngeal Swab or Saliva or Oral Swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.</p> <p>Class of medical device:Class C</p> <p>Material of construction:NA</p> <p>Dimension(if any):NA</p> <p>Shelflife:24 Months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Influenza A/B Antigen Test Kit</p>

Place:

Date:19-Feb-22

VENUGOPAL G SOMANI

Central Licensing Authority

Digitally signed by VENUGOPAL G SOMANI
DN: cn=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=DRUGS
CONTROLLER GENERAL (INDIA),
pseudonym=112046a34e21727bacb2557487
32c456d249073e55e953d9cb5b58748ee3113
c, postalCode=110002, st=DELHI,
serialNumber=977241aa0c0bba41522525ffc
a0705074b4997e6b2f4b55c8b81cf282adeaf5d,
cn=VENUGOPAL G SOMANI
Date: 2022.02.21 14:29:22 +05'30'