



सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000069

Endorsement No. 6

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, 4th Floor, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

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

3. 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	Generic Name:Chikungunya Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to Chikungunya virus Class of medical device:Class B 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 Chikungunya Antibody (IgG/IgM) Test Kit
2	Generic Name:Filaria Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is an immunoassay for the simultaneous detection and differentiation of anti-lymphatic filarial parasites (W.bancrofti and B.malayi) IgG and IgM in human serum, plasma, or whole blood. Class of medical device:Class B 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 Filaria Antibody (IgG/IgM) Test Kit

3	<p>Generic Name:H.Pylori Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:H. pylori Antibody Rapid Test is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM) against Helicobacter pylori (H. pylori) in human serum, plasma or whole blood. Class of medical device:Class B 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 H.Pylori Antibody (IgG/IgM) Test Kit</p>
---	---

Place:

Date20-May-22

Manmohan Taneja
Digitally signed by Manmohan Taneja
Date: 2022.05.20 10:04:33 +05'30'
State Licensing Authority

