



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. 3

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:Dengue NS1/IgG/IgM Combo RAPID Test Kit Model No.:PKRK005 - NA Intended Use:It is a solid phase immuno chromatographic assay for the rapid, qualitative and differential detection of NS1 antigen and IgG and IgM antibodies to dengue virus (DEN 1, DEN2, DEN3, and DEN4) in human serum, plasma or whole blood. 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 Dengue IgG/IgM/NS1 Combo detect kit; Dengue at Home IgG/IgM/NS1 Combo detect kit</p>
2	<p>Generic Name:Dengue NS1 Antigen RAPID Test Kit Model No.:PKRK003 - NA Intended Use:It is an immunoassay for the simultaneous and qualitative detection of dengue NS1 antigen (DEN 1, 2, 3, 4) in human serum, plasma or whole blood 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 Dengue NS1 Antigen detect kit; Dengue at home NS1 Antigen detect kit</p>

Place:

Date:15-Mar-22

Central Licensing Authority



From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Pvt. Ltd.,
Plot no. 28-29, Electronic City, Sec-18,
District- Gurgaon-122001 (Haryana)

Dated: 30-12-2021

Subject: Regarding additional items.

With reference to your application no. MFG/MD/2021/49394 dated 25.10.2021 on the subject cited above.

Find enclosed herewith copy of Form MD-5 Endorsement -3.

Enclosed:- As above.


State Drugs Controller
Food & Drugs Administration, Haryana
Licensing Authority
Food & Drugs Administration, Haryana



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. 3

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. 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:Dengue IgG/IgM Rapid Test Kit Model No.:PKRK004 - NA Intended Use:It is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to dengue virus 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 Dengue IgG/IgM antibody detect kit ; Dengue at home IgG/IgM antibody detect kit</p>

Place:

Date 30-Dec-21

Approved by No.....to.....
Exc State Licensing Authority.....

(Manmohan Taneja)
State Drugs Controller-cum-Controlling & Licensing Authority
Food & Drugs Administration, Haryana