

Regd.
From

State Drug Controller-Cum-Licensing Authority,
Department of Food & Drugs Administration, Haryana,
SCO.No. 94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Private Limited,
Plot no. 28-29, Electronic City, Sector-18, Gurugram

Memo No. 4/167-2D-I-2021/-9205

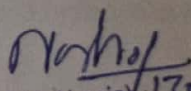
Dated: 13/07/2021

Subject: Regarding grant of license under Medical Devices Rules, 2017 to manufacture for sale or for distribution of class A or class B Medical Device.

Kindly reference to your letter no. Nil dated Nil the subject cited above.

Find enclosed herewith a copy of Form-MD-5 having Medical Devices (Class A or Class B) manufacturing license no. MFG/MD/2021/000069 w.r.t. 13.07.2021 to 12.07.2026. You are also directed to apply retention fee on or before 12.07.2026.

Encls As Above.


(N. K. Ahooja) 13/07/21
State Drugs Controller-cum-Controlling &
Licensing Authority
Food & Drugs Administration, Haryana

Endst No. 4/167-2D-I-2021/

A copy is forwarded to Senior Drugs Control Officer, Gurugram alongwith copy of form MD-5 with details of devices.

Dated:

(N. K. Ahooja)
State Drugs Controller-cum-Controlling &
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

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:Viral Transport Media Kit Model No.:PKTM001 - NA Intended Use:PK Viral Transport medium is a specially formulated medium for collection and transport of viruses. It is designed to maintain the optimum viability and virulence of the viral sample. Class of medical device:Class A Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PK Viral Transport Media Kit</p>
2	<p>Generic Name:Viral Lysis Transport Media Kit Model No.:PKTM002 - NA Intended Use:PK Viral Lysis Transport medium is a specially formulated medium for collection and transport of viruses. It is designed to maintain the optimum viability and virulence of the viral sample. Class of medical device:Class A Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PK Viral Lysis Transport Media Kit</p>

Accepted Item No. 13072
Except Sr. No. 2

(Signature)
M K Anoop 13072
State Drugs Controller-cum-Controlling & Licensing Authority
Food & Drugs Administration, Haryana

