

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/2021/48941 dated 26.10.2021 on the subject cited above.

Find enclosed herewith copy of Form MD-5 Endorsement -2.

Enclosed:- As above.


State Drugs Controller
State Drugs Controller-cum-Controlling & Licensing Authority
Food & Drugs Administration, Haryana
Food & Drugs Administration, Haryana



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. 2

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	Generic Name:Human Chorionic Gonadotropin (hCG) test kit Model No.:PKRK0016 - NA Intended Use:It determines the presence of hCG (Human Chorionic Gonadotropin) in urine samples. 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):PregAtHome Pregnancy Kit; PregAtHome Pregnancy Mini Kit
2	Generic Name:Human Chorionic Gonadotropin (hCG) Strip Model No.:PKUR001 - NA Intended Use:It determines the presence of hCG (Human Chorionic Gonadotropin) in urine samples. 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):PregAtHome Pregnancy Strip

3	<p>Generic Name:Luteinizing Hormone (LH) Test kit</p> <p>Model No.:PKRK019 - NA</p> <p>Intended Use:It is a rapid visual immunoassay for the qualitative, presumptive detection of luteinizing hormone in human urine specimens. This kit is for use as an aid in the detection of ovulation.</p> <p>Class of medical device:Class B</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):PregAtHome Ovulation Kit</p>
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Place:

Date 30-Dec-21

Approved *M* No. to
 State Licensing Authority
 Except S. No.

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

