



Food and Drugs Administration Haryana
SCO-94, SEC-5, Panchkula

From

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

To

M/s Pathkits Healthcare Pvt. Ltd.,
28-29, Electronic City,
Gurugram, Haryana

Dated: 04-01-2022

Subject: Regarding additional items.

With reference to your application no. MFG/IVD/2021/50175 dated 15.11.2021 on the subject cited above.

Find enclosed herewith copy of Form MD-5, Lic No MFG/IVD/2021/000069, Endorsement No 4.

Validity unknown
Digitally signed by Manmohan Taneja
Date: 2022.01.04 11:51:15



State Drugs Controller



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. 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. 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:Cervical Brush Collection Kit for HPV and Cytology Model No.:PKIVD001 - NA Intended Use:It is used for cervical screening aims to improve the quality of the conventional cervical smear through an improved slide preparation technique following collection of the sample in the standard way. Class of medical device:Class B Material of construction:NA Dimension(if any):Na Shelflife:18 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Cervical Brush Collection Kit for HPV and Cytology</p>

Place:

Date04-Jan-22

Validity unknown
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Date: 2022.01.04 11:57:13



State Licensing Authority