



**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.,  
4<sup>th</sup> Floor, 28, 29 Electronic City, Sector -18,  
Gurgaon, Haryana

Dated: 27-07-2022

**Subject: Regarding additional items.**

With reference to your application no. MFG/MD/2022/64911 dated 18.07.2022 on the subject cited above.

Find enclosed herewith copy of Form MD-5, Lic No MFG/IVD/2021/000069 Endorsement No 08.

Manmohan Taneja  
State Drugs Controller Haryana

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Manmohan Taneja  
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## 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. 8

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:Urine Test Strip (Ketone, Glucose) Model No.:NIL Intended Use:It is made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagents for diagnostics. It tests Ketone and Glucose in urine 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):URISelf (Ketone, Glucose)
2	Generic Name:Urine Test Strip (Leukocytes & Nitrites) Model No.:NIL Intended Use:It is made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagents for diagnostics. It tests Leukocytes and Nitrites in urine. 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 UTI DETECT (Leukocytes & Nitrites)

3	<p>Generic Name:Urine Test Strip (Protein, Glucose)  Model No.:NIL  Intended Use:It is made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagents for diagnostics. It tests Protein and Glucose in urine.  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):URISelf (Protein, Glucose)</p>
4	<p>Generic Name:Urine Test Strip (Glucose, Protein, Ketone, Blood &amp; Leucocytes)  Model No.:NIL  Intended Use:It is made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagents for diagnostics. It tests Glucose, Protein, Ketone, Blood and Leukocytes in urine.  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):URISelf Basic (5 Parameters)</p>
5	<p>Generic Name:Urine Test Strip (Glucose, Protein, Ketone, Blood, Leukocytes, Nitrites, pH, SG, Urobilinogen and Bilirubin)  Model No.:NIL  Intended Use:It is made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagents for diagnostics. It tests Glucose, Protein, Ketone, Blood, Leukocytes, Nitrites, pH, SG, Urobilinogen and Bilirubin in urine.  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):URISelf Pro (10 Parameters)</p>
6	<p>Generic Name:Urine Test Strip (Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ascorbic acid, Ketone, Bilirubin, Glucose, Micro albumin, Creatinine and Calcium)  Model No.:NIL  Intended Use:It is made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagents for diagnostics. It measures Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ascorbic acid, Ketone, Bilirubin, Glucose, Microalbumin, Creatinine and Calcium in urine.  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):URISelf Total (14 Parameters)</p>

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Manmohan Taneja  
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Place:

