



**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 PRIVATE LIMITED,  
4<sup>th</sup> Floor, 28, 29 Electronic City,  
Sector -18, Gurgaon, Haryana (India)

Dated: 16-08-2022

**Subject: Regarding additional items.**

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With reference to your application no. MFG/IVD/2022/66583 dated 04.08.2022 on the subject cited above.

Find enclosed herewith copy of Form MD-5, Lic No MFG/IVD/2021/000069 ,Endorsement No 9.

Manmohan  
Taneja

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Manmohan Taneja  
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State Drugs Controller Haryana



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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. 9

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:Typhoid Antibody (IgG/IgM) Test Kit Model No.:NIL Intended Use:It is a rapid test for the qualitative detection of IgG and IgM antibodies to Salmonella typhi (S. typhi) in human whole blood, serum or plasma. 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 Typhoid IgG/IgM

Place:

Date:16-Aug-22

Manmohan  
Taneja

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Manmohan Taneja  
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State Licensing Authority