Regd. From

The State Drug Controller-cum-Licensing Authority Food and Drugs Administration, Haryana, SCO No.94 Sector-5, Panchkula.

To

M/s Pathkits Healthcare Private Limited, Industrial Independent, Plot No. 28-29, Sector-18, Gurugram-122001.

Memo. No. 4/167-1Drug-1-2021/ /047/

Dated:

16/09/2021

Subject:

Regarding issuance of Non-Conviction Certificate.

With reference to your letter No. Nil dated 26.08.2021on the subject cited above.

Your application has been examined by this office and as per your request, the desired Non Conviction Certificate is hereby enclosed.

Encl. :- As above.

MANMOHAN TANEJA Assistant State Drugs Controller Food & Drugs Administration, PANCHKIII A (Haryana)

F NO: HR/NCC/IVD/2021/000014

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
Ministry of Health and Family welfare
(Medical Device and Diagnostic Division)
NON CONVICTION CERTIFICATE

Certificate Number: NCC/IVD/2021/000095

This is to certify that M/s. PATHKITS HEALTHCARE PRIVATE LIMITED situated at address 28, 29 Electronic City, Sector -18, Gurgaon Haryana, 122001,8588869343, India Gurgaon Haryana 122001 8588869343 India is holding Manufacturing/Import License no. MFG/IVD/2021/000069 dated 13-JUL-2021.

Based on the undertaking submitted by the firm, firm has not been convicted under Drugs and Cosmetics Act 1940 and rules thereunder.

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	Generic Name :Viral Transport Media Kit
	2. Brand Name :PK Viral Transport Media Kit
	3. Notified Category :Other than above substancesViral Transport Media Kit
	4. Class of Medical Device :Class A
	5. Shelf life :24 Months
	6. Sterile/Non-Sterile:Sterilized
	7. 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.
	8. Material of Construction: NA
	9. Dimension: NA
	10. Model/Catalogue No./Name :PKTM001 - NA
2	Generic Name :Viral Lysis Transport Media Kit
	2. Brand Name :PK Viral Lysis Transport Media Kit
	3. Notified Category :Other than above substancesViral Lysis Transport Media Kit
	4. Class of Medical Device :Class A
	5. Shelf life :24 Months
	6. Sterile/Non-Sterile:Sterilized
	7. 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 viabilit
	and virulence of the viral sample.
	8. Material of Construction: NA
	9. Dimension: NA
	10. Model/Catalogue No./Name :PKTM002 - NA

Dated: 16-Sep-2021

	And the Party of t	17.18
 1. Generic Name :Univers	al Transport	Media Kit
1. Generic Name :Univers	ocal fire in	- sendia M

- 3. Notified Category :Other than above substancesUniversal Transport Media Kit 2. Brand Name : PK Universal Transport Media Kit
- 4. Class of Medical Device : Class A
- 5. Shelf life :24 Months
- 7. Intended Use :PK Universal Transport medium is a specially formulated medium for 6. Sterile/Non-Sterile:Sterilized collection and transport of viruses. It is designed to maintain the optimum viability and virulence of the viral sample.
- 8. Material of Construction: NA
- 9. Dimension: NA
- 10. Model/Catalogue No./Name :PKTM003 NA

MANMOHAN TANEJA Assistant State Drugs Controller Food & Drugs Administration, PANCHICE TO (Haprine) F NO: HR/FSC/IVD/2021/000033

Government of India Directorate General of Health Services Central Drugs Standard Control Organisation Ministry of Health and Family welfare

FREE SALE CERTIFICATE

FSC Number: FSC/IVD/2021/000106 Dated: 14/09/2021

This is to certify that M/s. PATHKITS HEALTHCARE PRIVATE LIMITED situated at address 28, 29 Electronic City, Sector -18, Gurgaon Haryana, 122001,8588869343, India is holding Manufacturing License no. MFG/IVD/2021/000069 issued on 13-JUL-2021 Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	Generic Name :Viral Transport Media Kit
	2. Brand Name :PK Viral Transport Media Kit
	3. Notified Category :Other than above substancesViral Transport Media Kit
	4. Class of Medical Device :Class A
	5. Shelf life :24 Months
	6. Sterile/Non-Sterile:Sterilized
	7. 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.
	8. Material of Construction: NA
	9. Dimension: NA
	10. Model/Catalogue No./Name :PKTM001 - NA
2	Generic Name :Viral Lysis Transport Media Kit
	2. Brand Name :PK Viral Lysis Transport Media Kit
	3. Notified Category :Other than above substancesViral Lysis Transport Media Kit
	4. Class of Medical Device :Class A
	5. Shelf life :24 Months
	6. Sterile/Non-Sterile:Sterilized
	7. 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.
	8. Material of Construction: NA
	9. Dimension: NA
	10. Model/Catalogue No./Name :PKTM002 - NA

MANMOHAN TANEJA
Assistant State Drugs Controller
Food & Drugs Administration,
PANCHKUI A (Heryans) Q

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- 1. Generic Name : Universal Transport Media Kit
- 2. Brand Name : PK Universal Transport Media Kit
- 3. Notified Category :Other than above substancesUniversal Transport Media Kit
- 4. Class of Medical Device : Class A
- 5. Shelf life :24 Months
- 6. Sterile/Non-Sterile:Sterilized
- 7. Intended Use :PK Universal 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.
- 8. Material of Construction: NA
- 9. Dimension: NA
- 10. Model/Catalogue No./Name :PKTM003 NA

MANMOHAN TANELA

Asset ant State Orthon Controller
Food & Drugs Administration,
PANCHKIII A (Haryana)