



सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2021/000068

Endorsement No. 1

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. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. 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:RNA Extraction kit Model No.:PKEXT002 - NA Intended Use:Viral RNA Extraction Kit is for the extraction,enrichment and purification of nucleic acid(RNA) in samples.It proceeds products are for clinical in vitro diagnostics for medical professionals. Class of medical device:Class C Material of construction:Medical Grade Plastic , Chemical Reagents, Filter, Silica Gel Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PK Rapid viral RNA extraction kit</p>
2	<p>Generic Name:RNA Extraction Kit Model No.:PKEXT001 - NA Intended Use:Viral RNA Extraction Kit (Magnetic Beads Method) is for extraction, enrichment and purification of nucleic acid (RNA) in samples] Class of medical device:Class C Material of construction:Medical Grade Plastic, Chemical Reagent, Magnetic Beads Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PK Magnetic Viral RNA Extraction Kit</p>

Place:

Date:13-Aug-21

Central Licensing Authority

