

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/2024/000079

Dated : 03/05/2024

This is to certify that M/s. PARAMCARE LIFE SCIENCES PRIVATE LIMITED ,PARAMCARE LIFE SCIENCES PRIVATE LIMITED situated at address G/F-12/13, EVERSHINE-2, SURVEY NO. 307/3/1, BALITHA N.H NO 48, VAPI ,Valsad Gujarat ,396191,9821056409, India is holding Manufacturing License no. MFG/IVD/2022/000123 issued on 07-NOV-2022 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 |
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| 1 | <p>1. Generic Name :CRP Turbilatex Test Kit</p> <p>2. Brand Name :NIL</p> <p>3. Notified Category :Other than above substancesIn vitro diagnostic devices for CRP Turbilatex</p> <p>4. Class of Medical Device :Class C</p> <p>5. Shelf life :18 Months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :CRP Turbilatex Test Kit is intended for Quantitative determination of C - reactive protein in serum / Plasma.</p> <p>8. Material of Construction: Reagent 1: Buffer Reagent, Reagent 2: Latex Reagent, Calibrator : 60 mg/L</p> <p>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :NIL</p> |

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| 2 | <ol style="list-style-type: none"> 1. Generic Name :Malaria Pf/Pv Ag Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Malaria Pf/Pv 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Malaria Pf/Pv Antigen Rapid Test Kit is intended for qualitative determination of Malaria P. falciparum and Malaria P. Vivax infection in human blood. 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal Antibody for P. falciparum histidine rich protein-2 (pf HRP II) and another monoclonal antibody (test line 2) for lactate Dehydrogenase (Pan LDH) of plasmodium Vivax (P.Vivax) on the Pf & PV test line region of the device respectively and Antibody for Control, Gold Conjugate Pad: Gold conjugated recombinant Monoclonal Antibody for P. falciparum histidine rich protein-2 (pf HRP II) and another monoclonal antibody (test line 2) is pan specific to lactate Dehydrogenase (Pan LDH) of plasmodium Vivax (P.Vivax) for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL |
| 3 | <ol style="list-style-type: none"> 1. Generic Name :Salmonella Typhi and Paratyphi 'A' antigen Rapid Test Kit 2. Brand Name :RapiChex 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Salmonella Typhi and Paratyphi 'A' antigen 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Salmonella Typhi and Paratyphi 'A' antigen Rapid Test Kit is intended for qualitative determination of Salmonella Typhi and Paratyphi 'A' antigen in human Serum and stool sample 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Monoclonal Antibody for Salmonella Typhi and another monoclonal antibody (test line 2) for Salmonella Paratyphi on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated recombinant Monoclonal Antibody for Salmonella Typhi and another monoclonal antibody (test line 2) for Salmonella Paratyphi for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :PTYA/Salmonella Typhi Paratyphi A Antigen - Salmonella Typhi and Paratyphi A antigen Rapid Test Kit is intended for qualitative determination of Salmonella Typhi and Paratyphi A antigen in human Serum and stool sample, - |

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| 4 | <ol style="list-style-type: none"> 1. Generic Name :Syphilis Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Syphilis 4. Class of Medical Device :Class D 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The Syphilis Rapid Test is a rapid test that qualitatively detects the presence of Treponema specific antibodies of syphilis in Whole blood/Serum/Plasma specimens within 15 minutes . 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with recombinant Syphilis Antigen on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated recombinant Syphilis Antigen for test and Antibody for control are coated on Glass fiber pad , Sample Release Pad , Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL |
| 5 | <ol style="list-style-type: none"> 1. Generic Name :H.Pylori Ag Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for H. Pylori 4. Class of Medical Device :Class C 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :H. Pylori Ag Rapid Test Kit is intended for qualitative determination of Helicobacter Pylori Antigen presence in human Stool sample. 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with Anti-Helicobacter Pylori Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Anti-Helicobacter Pylori Antibody for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL |

Competent Authority