

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

FREE SALE CERTIFICATE

FSC Number : FSC/IVD/2024/000080

Dated : 04/05/2024

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/2022/000096 issued on 07-SEP-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
1	1. Generic Name :Glucose Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Glucose 4. Class of Medical Device :Class B 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Glucose Test Kit is intended for Quantitative determination of Glucose in Serum / Plasma / Urine. 8. Material of Construction: Reagent I-Glucose Reagent, Glucose standard-100 mg/dl (5.54 mmol/L) 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
2	1. Generic Name :Lactate Dehydrogenase (LDH) Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Lactate Dehydrogenase 4. Class of Medical Device :Class B 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lactate Dehydrogenase (LDH) (L-P) Test Kit is intended for Quantitative determination of Lactate Dehydrogenase (LDH) in serum / Plasma. 8. Material of Construction: Reagent 1-Buffer reagent, Reagent 2-Substrate reagent 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

3	<ol style="list-style-type: none"> 1. Generic Name :Ferritin Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Ferritin 4. Class of Medical Device :Class B 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Ferritin Rapid Test Kit (Serum/Plasma/Whole blood) qualitatively detects the presence of ferritin protein in Whole blood/Serum/Plasma specimens within 15 minutes. 8. Material of Construction: Nitrocellulose Membrane: The membrane coated with recombinant Ferritin Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated recombinant Ferritin 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
4	<ol style="list-style-type: none"> 1. Generic Name :Vitamin D Rapid Test Kit 2. Brand Name :NIL 3. Notified Category :Other than above substancesIn vitro diagnostic devices for Vitamin D 4. Class of Medical Device :Class B 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Vitamin D Rapid Test Kit (Serum/Plasma/Whole blood) detects the presence of Vitamin D in Whole blood/Serum/Plasma specimens within 15 minutes. 8. Material of Construction: Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

Competent Authority