



सत्यमेव जयते

## 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/2022/000096**

Endorsement No. **15**

- M/s PARAMCARE LIFE SCIENCES PRIVATE LIMITED, C-609, MITTAL COMMERCIAL CO-OP SOC LTD., NEAR MITTAL ESTATE, OFF M.V.ROAD, MAROL, ANDHERI,MUMBAI, Mumbai Suburban, Maharashtra (India) - 400059 Telephone No.: 9821056409 FAX: 9821056409** has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at **M/s PARAMCARE LIFE SCIENCES PRIVATE LIMITED, G/F-12/13, EVERSHINE-2, SURVEY NO. 307/3/1, BALITHA N.H NO 48, VAPI, Valsad, Gujarat (India) - 396191 Telephone No.: 9821056409 FAX: 9821056409**
- Details of medical device(s) [Annexed]

- 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><b>Generic Name:</b>HbA1c Rapid Test Kit  <b>Model No.:</b>NIL  <b>Intended Use:</b>The Paramcare HbA1c Rapid Test Kit (Whole Blood) qualitatively detects the presence of HbA1c in Whole Blood specimens within 10 minutes.  <b>Class of medical device:</b>Class B  <b>Material of construction:</b>1. Nitrocellulose Membrane: The membrane coated with recombinant HbA1c Antibody on the test line region of the device and Antibody for Control. 2. Gold Conjugate Pad: Gold conjugated recombinant HbA1c Antibody for test and Antibody for control are coated on Glass fiber pad 3. Sample Release Pad 4. Absorbent Pad  <b>Dimension(if any):</b>  <b>Shelflife:</b>24 months  <b>Sterile or Non sterile:</b>Non-Sterilized  <b>Brand Name(if registered under the Trade Marks Act, 1999):</b>NIL</p>
2	<p><b>Generic Name:</b>TSH Rapid Test Kit  <b>Model No.:</b>NIL  <b>Intended Use:</b>TSH Rapid Test is a rapid test that qualitatively detects the presence of TSH in human serum/plasma/whole blood specimen at the sensitivity of 5 mIU/L. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of TSH in serum/plasma/whole blood.  <b>Class of medical device:</b>Class B  <b>Material of construction:</b>1. Nitrocellulose Membrane: The membrane coated with Monoclonal Anti-TSH Antibodies on the test line region of the device and Antibody for Control. 2. Gold Conjugate Pad: Gold conjugated Monoclonal Anti-TSH Antibodies for test and Antibody for control are coated on Glass fiber pad 3. Sample Release Pad 4. Absorbent Pad  <b>Dimension(if any):</b>  <b>Shelflife:</b>24 months  <b>Sterile or Non sterile:</b>Non-Sterilized  <b>Brand Name(if registered under the Trade Marks Act, 1999):</b>NIL</p>

Place: GANDHINAGAR

Date 01-May-25

State Licensing Authority

