

**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/2025/000046

Dated : 11-Feb-2025

This is to certify that M/s. **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 Valsad Gujarat 396191 9821056409 India** is holding Manufacturing/Import License no. **MFG/IVD/2022/000123** dated **07-NOV-2022**.

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	<b>1. Generic Name :</b> Troponin I Rapid Test Kit <b>2. Brand Name :</b> NIL <b>3. Notified Category :</b> Other than above substances In vitro diagnostic device for Troponin I <b>4. Class of Medical Device :</b> Class C <b>5. Shelf life :</b> 24 months <b>6. Sterile/Non-Sterile:</b> Non-Sterilized <b>7. Intended Use :</b> Troponin I Rapid Test is a rapid test that qualitatively detects the presence of cTnI in human serum/plasma/whole blood specimen at the sensitivity of 0.5 ng/mL. <b>8. Material of Construction:</b> Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad <b>9. Dimension:</b> NA <b>10. Model/Catalogue No./Name :</b> NIL
2	<b>1. Generic Name :</b> Troponin T Rapid Test Kit <b>2. Brand Name :</b> NIL <b>3. Notified Category :</b> Other than above substances In vitro diagnostic device for Troponin T <b>4. Class of Medical Device :</b> Class C <b>5. Shelf life :</b> 24 months <b>6. Sterile/Non-Sterile:</b> Non-Sterilized <b>7. Intended Use :</b> Troponin T Rapid Test is a rapid test that qualitatively detects the presence of Cardiac Troponin T (cTnT) in human serum/plasma/whole blood specimen at the sensitivity of 0.5 ng/mL. <b>8. Material of Construction:</b> Nitrocellulose Membrane, Gold Conjugate Pad, Sample Release Pad, Absorbent Pad <b>9. Dimension:</b> NA <b>10. Model/Catalogue No./Name :</b> NIL

3	<p><b>1. Generic Name :</b>Influenza A+B Rapid Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Influenza A+B</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>Influenza A+B Rapid Test Kit is a rapid test that aid in the qualitative detection and differentiation of Influenza A virus (including H5N1 and H1N1), and Influenza B in in nasopharyngeal swab or nasal aspirate specimens. The test utilizes a combination of anti-influenza A +B antibodies.</p> <p><b>8. Material of Construction:</b> Influenza A+B Ag Rapid test is a lateral flow immuno-chromatographic assay which utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology. The test device is designed to detect antigens from influenza A, and /or influenza B in anterior nasal or nasopharyngeal swab specimens from individuals with signs and symptoms of respiratory infection, suspected of flu by their healthcare provider, within the first five days of onset of symptoms. It is intended to aid in the rapid differential diagnosis of influenza A, and /or influenza B viral infections.</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
4	<p><b>1. Generic Name :</b>Rapid Drugs (Amphetamine) Screening Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Amphetamine</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>The Rapid Drugs (Amphetamine) Screening Test Kit is a rapid test that qualitatively detects the presence of Amphetamines in human urine specimen at the cut off value of 1000 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Amphetamines to detect Amphetamines in human urine sample</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated AMP on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-AMP Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
5	<p><b>1. Generic Name :</b>Rapid Drugs (Barbiturates) Screening Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Barbiturates</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>The Rapid Drugs (Barbiturates) Screening Test Kit is a rapid test that qualitatively detects the presence of Barbiturates in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Barbiturates to detect Barbiturates in human urine sample</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated BAR on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-BAR Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>

6	<p><b>1. Generic Name :</b>The Rapid Drugs (Benzodiazepines) Screening Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Benzodiazepines</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>The Rapid Drugs (Benzodiazepines) Screening Test Kit is a rapid test that qualitatively detects the presence of Benzodiazepines in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Benzodiazepines to detect Benzodiazepines in human urine sample</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated BZO on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-BZO Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
7	<p><b>1. Generic Name :</b>Rapid Drugs (Cocaine) Screening Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Cocaine</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>The Rapid Drugs (Cocaine) Screening Test Kit is a rapid test that qualitatively detects the presence of Cocaine in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Cocaine to detect Cocaine in human urine sample</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated COC on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-COC Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
8	<p><b>1. Generic Name :</b>Rapid Drugs (Opiate (Morphine)) Screening Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Opiate (Morphine)</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>The Rapid Drugs (Opiate (Morphine)) Screening Test Kit is a rapid test that qualitatively detects the presence of Opiate (Morphine) in human urine specimen at the cut off value of 300 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Opiate (Morphine) to detect Opiate (Morphine) in human urine sample</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated OPI on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-OPI Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>

9	<p><b>1. Generic Name :</b>Rapid Drugs (Cannabinoids) Screening Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Cannabinoids</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>The Rapid Drugs (Cannabinoids) Screening Test Kit is a rapid test that qualitatively detects the presence of Cannabinoids in human urine specimen at the cut off value of 50 ng/mL. The test utilizes a combination of monoclonal antibody and BSA conjugated Cannabinoids to detect Cannabinoids in human urine sample</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated THC on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti-THC Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
10	<p><b>1. Generic Name :</b>Rapid Multi Drugs (6 in 1(Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate) Screening Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Rapid Multi Drugs</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>Rapid Multi Drugs (6 in 1(Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC, Opiate) Screening Test Kit is a rapid test that qualitatively detects the presence of Cocaine (300 ng/ml), Amphetamine (1000 ng/ml), Barbiturate (300 ng/ml), Benzodiazepine (300 ng/ml), THC (50 ng/ml) and Opiate (300 ng/ml) in human urine specimen at the cut off value. The test utilizes a combination of monoclonal antibody and BSA conjugated Cocaine, Amphetamine, Barbiturate, Benzodiazepine, THC and Opiate to detect in human urine sample.</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Monoclonal BSA conjugated AMP, OPI and COC is one membrane and THC, BZO and BAR on another membrane test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated Monoclonal Anti- COC, AMP, BZO, THC, and OPI Antibodies for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
11	<p><b>1. Generic Name :</b>Dengue NS 1 Ag Rapid Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Dengue NS 1 Ag</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>Dengue NS1 Ag Rapid Test Kit is intended for qualitative determination of NS1 Ag for dengue virus in human Serum/Plasma/Whole Blood.</p> <p><b>8. Material of Construction:</b> 1. Nitrocellulose Membrane: The membrane coated with Anti-Dengue NS1 Antibody on the test line region of the device and Antibody for Control. 2. Gold Conjugate Pad: Gold conjugated Anti-Dengue NS1 Antibody for test and Antibody for control are coated on Glass fiber pad 3. Sample Release Pad 4. Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>

12	<p><b>1. Generic Name :</b>CRP Turbilatex Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for CRP Turbilatex</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>18 Months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>CRP Turbilatex Test Kit is intended for Quantitative determination of C - reactive protein in serum / Plasma.</p> <p><b>8. Material of Construction:</b> Reagent 1: Buffer Reagent, Reagent 2: Latex Reagent, Calibrator : 60 mg/L</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
13	<p><b>1. Generic Name :</b>Malaria Pf/Pv Ag Rapid Test Kit</p> <p><b>2. Brand Name :</b>NIL</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Malaria Pf/Pv</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>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.</p> <p><b>8. Material of Construction:</b> 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 &amp; 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</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>NIL</p>
14	<p><b>1. Generic Name :</b>Salmonella Typhi and Paratyphi 'A' antigen Rapid Test Kit</p> <p><b>2. Brand Name :</b>RapiChex</p> <p><b>3. Notified Category :</b>Other than above substancesIn vitro diagnostic devices for Salmonella Typhi and Paratyphi 'A' antigen</p> <p><b>4. Class of Medical Device :</b>Class C</p> <p><b>5. Shelf life :</b>24 months</p> <p><b>6. Sterile/Non-Sterile:</b>Non-Sterilized</p> <p><b>7. Intended Use :</b>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</p> <p><b>8. Material of Construction:</b> 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</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b>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, -</p>

15	<p><b>1. Generic Name :</b> Syphilis Rapid Test Kit</p> <p><b>2. Brand Name :</b> NIL</p> <p><b>3. Notified Category :</b> Other than above substances In vitro diagnostic devices for Syphilis</p> <p><b>4. Class of Medical Device :</b> Class D</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> 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 .</p> <p><b>8. Material of Construction:</b> 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</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> NIL</p>
16	<p><b>1. Generic Name :</b> H. Pylori Ag Rapid Test Kit</p> <p><b>2. Brand Name :</b> NIL</p> <p><b>3. Notified Category :</b> Other than above substances In vitro diagnostic devices for H. Pylori</p> <p><b>4. Class of Medical Device :</b> Class C</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> H. Pylori Ag Rapid Test Kit is intended for qualitative determination of Helicobacter Pylori Antigen presence in human Stool sample.</p> <p><b>8. Material of Construction:</b> 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</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> NIL</p>
17	<p><b>1. Generic Name :</b> Sickel Cell Hb S, Hb A and Hb C Rapid Test Kit</p> <p><b>2. Brand Name :</b> NIL</p> <p><b>3. Notified Category :</b> Other than above substances In vitro diagnostic devices for Sickel Cell</p> <p><b>4. Class of Medical Device :</b> Class C</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> Sickel Cell Rapid Test Kit is a qualitative screening test for the detection of hemoglobin A, S and C in blood.</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with Sickel cell HbA and HbS Antibodies on the test line region of the device and Goat anti-mouse IgG Antibody for Control, Gold Conjugate Pad: Gold conjugated with Anti Sickel cell HbA and HbS Antibodies for Test, and Mouse IgG Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> NIL</p>
18	<p><b>1. Generic Name :</b> Ethyl Glucuronide (ETG) Rapid Test Kit</p> <p><b>2. Brand Name :</b> NIL</p> <p><b>3. Notified Category :</b> Other than above substances In vitro diagnostic devices for Ethyl Glucuronide</p> <p><b>4. Class of Medical Device :</b> Class C</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> The Ethyl Glucuronide (ETG) Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Ethyl Glucuronide (ETG) in human Urine specimens.</p> <p><b>8. Material of Construction:</b> Nitrocellulose Membrane: The membrane coated with recombinant Ethyl Glucuronide Antibody on the test line region of the device and Antibody for Control, Gold Conjugate Pad: Gold conjugated recombinant Ethyl Glucuronide Antibody for test and Antibody for control are coated on Glass fiber pad, Sample Release Pad, Absorbent Pad</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> NIL</p>

19	<p><b>1. Generic Name :</b> Blood Grouping Sera Anti-A (IgM)</p> <p><b>2. Brand Name :</b> SeroChex</p> <p><b>3. Notified Category :</b> Substances used for in vitro diagnosis including Blood Grouping Sera</p> <p><b>4. Class of Medical Device :</b> Class D</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> The Anti-A reagent is used in the red blood cell determination of the A blood group. They are used to determine the absence or presence of erythrocytic antigens A on the surface of human red blood cells.</p> <p><b>8. Material of Construction:</b> Anti-A Monoclonal Reagent contain reactive components monoclonal antibodies of the immunoglobulin class IgM. Antibodies are diluted in a buffered protein solution containing bovine albumin, ethylenediamine tetraacetate (EDTA) and colorant Patent Blue (Anti-A).</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> PBGA 10 - 1X 10 mL ,PBGA 30 - 3 X10 mL ,PBGA 40 - 4 X 10 mL ,PBGA 100 - 10X 10 mL ,PBGA 1000 - 1X 1000 mL ,PBGA 5000 - 1 X5000 mL</p>
20	<p><b>1. Generic Name :</b> Blood Grouping Sera Anti-B (IgM)</p> <p><b>2. Brand Name :</b> SeroChex</p> <p><b>3. Notified Category :</b> Substances used for in vitro diagnosis including Blood Grouping Sera</p> <p><b>4. Class of Medical Device :</b> Class D</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> The Anti-B reagent is used in the red blood cell determination of the B blood group. They are used to determine the absence or presence of erythrocytic antigens B on the surface of human red blood cells.</p> <p><b>8. Material of Construction:</b> Anti-B Monoclonal Reagent contain reactive components monoclonal antibodies of the immunoglobulin class IgM. Antibodies are diluted in a buffered protein solution containing bovine albumin, ethylenediamine tetraacetate (EDTA) and colorant Tartrazine (Anti-B).</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> PBGB 10 - 1X 10 mL ,PBGB 30 - 3 X10 mL ,PBGB 40 - 4 X 10 mL ,PBGB 100 - 10X 10 mL ,PBGB 1000 - 1X 1000 mL ,PBGB 5000 - 1 X5000 mL</p>
21	<p><b>1. Generic Name :</b> Blood Grouping Sera Anti-AB (IgM)</p> <p><b>2. Brand Name :</b> SeroChex</p> <p><b>3. Notified Category :</b> Substances used for in vitro diagnosis including Blood Grouping Sera</p> <p><b>4. Class of Medical Device :</b> Class D</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> The Anti-AB reagent is used in the red blood cell determination of the AB blood group. They are used to determine the absence or presence of erythrocytic antigens A &amp; B on the surface of human red blood cells.</p> <p><b>8. Material of Construction:</b> Anti-AB Monoclonal Reagent contain reactive components monoclonal antibodies of the immunoglobulin class IgM. Antibodies are diluted in a buffered protein solution containing bovine albumin, ethylenediamine tetraacetate (EDTA).</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> PBAB 10 - 1X 10 mL ,PBAB 40 - 4 X 10 mL ,PBAB 100 - 10 X 10 mL ,PBAB 1000 - 1X 1000 mL ,PBAB 5000 - 1 X5000 mL</p>
22	<p><b>1. Generic Name :</b> Blood Grouping Sera Anti-D (IgG/IgM)</p> <p><b>2. Brand Name :</b> SeroChex</p> <p><b>3. Notified Category :</b> Substances used for in vitro diagnosis including Blood Grouping Sera</p> <p><b>4. Class of Medical Device :</b> Class D</p> <p><b>5. Shelf life :</b> 24 months</p> <p><b>6. Sterile/Non-Sterile:</b> Non-Sterilized</p> <p><b>7. Intended Use :</b> Anti-D IgG/IgM is intended for detection of Rhesus D Antigen and Weak Du Human Red Blood Cells.</p> <p><b>8. Material of Construction:</b> Anti-D IgG/IgM blend Reagent contains reactive components monoclonal antibodies of the immunoglobulin class IgM. Antibodies are diluted in a buffered protein solution containing bovine albumin, and ethylenediamine tetraacetate (EDTA).</p> <p><b>9. Dimension:</b> NA</p> <p><b>10. Model/Catalogue No./Name :</b> PBGD 10 - 1X 10 mL ,PBGD 30 - 3 X10 mL ,PBGD 40 - 4 X 10 mL ,PBGD 100 - 10X 10 mL ,PBGD 1000 - 1X 1000 mL ,PBGD 5000 - 1 X5000 mL</p>

