

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/2024/000174**

Dated : 18/09/2024

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
1	<p>1. Generic Name :Blood Grouping Sera Anti-A (IgM) 2. Brand Name :SeroChex 3. Notified Category :Substances used for in vitro diagnosis including Blood Grouping Sera 4. Class of Medical Device :Class D 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :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. 8. Material of Construction: 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). 9. Dimension: NA 10. Model/Catalogue No./Name :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>
2	<p>1. Generic Name :Blood Grouping Sera Anti-B (IgM) 2. Brand Name :SeroChex 3. Notified Category :Substances used for in vitro diagnosis including Blood Grouping Sera 4. Class of Medical Device :Class D 5. Shelf life :24 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :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. 8. Material of Construction: 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). 9. Dimension: NA 10. Model/Catalogue No./Name :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>

3	<p>1. Generic Name :Blood Grouping Sera Anti-AB (IgM)</p> <p>2. Brand Name :SeroChex</p> <p>3. Notified Category :Substances used for in vitro diagnosis including Blood Grouping Sera</p> <p>4. Class of Medical Device :Class D</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :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 & B on the surface of human red blood cells.</p> <p>8. Material of Construction: 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>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :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>
4	<p>1. Generic Name :Blood Grouping Sera Anti-D (IgG/IgM)</p> <p>2. Brand Name :SeroChex</p> <p>3. Notified Category :Substances used for in vitro diagnosis including Blood Grouping Sera</p> <p>4. Class of Medical Device :Class D</p> <p>5. Shelf life :24 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Anti-D IgG/IgM is intended for detection of Rhesus D Antigen and Weak Du Human Red Blood Cells.</p> <p>8. Material of Construction: 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>9. Dimension: NA</p> <p>10. Model/Catalogue No./Name :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>

Competent Authority