

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/2020/000020

Dated : 27/10/2020

This is to certify that M/s. M/s. Agappe Diagnostics Ltd. situated at address X/283C, Agappe Hills, Chengara, Pattimattom P.O., Ernakulam ,Ernakulam Kerala ,683562,04842867000, India is holding Manufacturing License no. MFG/IVD/2020/000005 issued on 18-JAN-2020 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 :CHOLINESTERASE KIT 2. Brand Name :CHOLINESTERASE KIT 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of cholinesterase in serum, plasma & urine. 8. Material of Construction: CHOLINESTERASE R1 and CHOLINESTERASE R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
2	1. Generic Name :CHOLINESTERASE S.L Kit 2. Brand Name :CHOLINESTERASE S.L Kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of CHOLINESTERASE S.L in serum,plasma & urine. 8. Material of Construction: CHOLINESTERASE S.L R1 and CHOLINESTERASE S.L R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

3	<ol style="list-style-type: none"> 1. Generic Name :25- Hydroxy Vitamin D Calibrator 2. Brand Name :25- Hydroxy Vitamin D Calibrator 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for 25- Hydroxy Vitamin D estimation. 8. Material of Construction: 25- Hydroxy Vitamin D Calibrator and Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
4	<ol style="list-style-type: none"> 1. Generic Name :25- Hydroxy Vitamin D Control 2. Brand Name :25- Hydroxy Vitamin D Control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :25- Hydroxy Vitamin D Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of 25-Hydroxy vitamin D in human serum. 8. Material of Construction: 25 OH Vitamin D Control and Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
5	<ol style="list-style-type: none"> 1. Generic Name :25- Hydroxy Vitamin D 2. Brand Name :25- Hydroxy Vitamin D 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the estimation of Vitamin D in human serum. 8. Material of Construction: 25- Hydroxy Vitamin D R1 and 25- Hydroxy Vitamin D R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
6	<ol style="list-style-type: none"> 1. Generic Name :ACID PHOSPHATASE Kit 2. Brand Name :ACID PHOSPHATASE Kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of ACID PHOSPHATASE in serum or plasma. - Direct Biuret Method - Linear up to 15 g/dL 8. Material of Construction: Potassium Iodide, Potassium sodium tartarate, Copper Sulphate, Sodium Hydroxide 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

7	<ol style="list-style-type: none"> 1. Generic Name :ACID WASHING SOLUTION 2. Brand Name :ACID WASHING SOLUTION 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Acid wash detergent is intended for cleansing and maintenance of reaction cuvettes and as BiOLis 24i automated clinical analyzer. 8. Material of Construction: Acid solution Stabilizer and Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
8	<ol style="list-style-type: none"> 1. Generic Name :ACID WASHING SOLUTION BIANCH 3 2. Brand Name :ACID WASHING SOLUTION BIANCH 3 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch 3 is intended for cleansing and maintenance of reaction cuvette and aspiration probes. (For extensive cleaning of cuvettes) of TOSHIBA (TBA Series) fully automated random access clinical chemistry analyzer series. 8. Material of Construction: Citric acid (concentrated) Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
9	<ol style="list-style-type: none"> 1. Generic Name :Acid Washing solution for TBA series of fully auto analyzers (TBA Wash Solution 3) 2. Brand Name :Acid Washing solution for TBA series of fully auto analyzers (TBA Wash Solution 3) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch 3 is intended for cleansing and maintenance of reaction cuvette and aspiration probes. (For extensive cleaning of cuvettes) of TOSHIBA (TBA Series) fully automated random access clinical chemistry analyzer series. 8. Material of Construction: Citric acid (concentrated) Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
10	<ol style="list-style-type: none"> 1. Generic Name :ACID WASHING SOLUTION (WASHING SOLUTION (AC) 2. Brand Name :ACID WASHING SOLUTION (WASHING SOLUTION (AC) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Acid wash detergent is intended for cleansing and maintenance of reaction cuvettes and aspiration probes of BiOLis 24i automated clinical analyzer. 8. Material of Construction: Acid solution Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

<p>1 1</p>	<p>1. Generic Name :Aga1c(hba1c Reagent) 2. Brand Name :Aga1c(hba1c Reagent) 3. Notified Category :Other than above substancesAga1c Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of % hba1c in human blood. 8. Material of Construction: Hba1c Direct 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL</p>
<p>12</p>	<p>1. Generic Name :AGHDL HDL-CHOLESTEROL 2. Brand Name :AGHDL HDL-CHOLESTEROL 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of AGHDL HDL-Cholesterol in human serum 8. Material of Construction: Reagent 1 R1: N—ethyl-N-(3-methylphenyl) -N' succinylethyenediame (EMSE) Reagent R2 Cholesterol Oxidase 4-Aminoantipyrin 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL</p>
<p>13</p>	<p>1. Generic Name :AGLDL LDL Cholesterol 2. Brand Name :AGLDL LDL Cholesterol 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of LDL-Cholesterol in human serum. 8. Material of Construction: Reagent 1 R1: HSDA, Goods buffer. Reagent R2: Cholesterol esterase , Cholesterol oxidase ,4-Aminoantipyrin ,Good's buffer 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL</p>
<p>14</p>	<p>1. Generic Name :Albumin kit 2. Brand Name :Albumin kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of albumin in serum or plasma. 8. Material of Construction: Succinate Buffer (pH4.20) 75 mmol/L Bromocresol green 0.14 g/L 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL</p>

15	<ol style="list-style-type: none"> 1. Generic Name :Albumin & Total Protein test kit 2. Brand Name :Albumin & Total Protein test kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Albumin & Total Protein in serum or plasma. 8. Material of Construction: Succinate Buffer (pH4.20) 75 mmol/L Bromocresol green 0.14 g/L 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
16	<ol style="list-style-type: none"> 1. Generic Name :ALKALINE CLEANING SOLUTION 2. Brand Name :ALKALINE CLEANING SOLUTION 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Alkaline washing detergent intended for cleansing and maintenance of reaction cuvette and aspiration probes of BiOLis 24i automated clinical analyzer. 8. Material of Construction: Alkaline solution (concentrated) Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
17	<ol style="list-style-type: none"> 1. Generic Name :ALKALINE CLEANING SOLUTION BIANCH 14 2. Brand Name :ALKALINE CLEANING SOLUTION BIANCH 14 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch 14 is the alkaline detergent intended for cleansing and maintenance of reaction cuvette and aspiration probes of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series. 8. Material of Construction: Sodium Hydroxide (concentrated) Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
18	<ol style="list-style-type: none"> 1. Generic Name :ALKALINE PHOSPHATASE Kit 2. Brand Name :ALKALINE PHOSPHATASE Kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Alkaline Phosphatase in serum or plasma. 8. Material of Construction: Magnesium Chloride - -0.625mmol/L. ALKALINE PHOSPHATASE R2 - P-Nitro phenyl phosphate (.) R2 50 mmol /L 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

19	<ol style="list-style-type: none"> 1. Generic Name :ALKALINE PHOSPHATASE S.L. Kit 2. Brand Name :ALKALINE PHOSPHATASE S.L. Kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Alkaline Phosphatase in serum or plasma. 8. Material of Construction: ALKALINE PHOSPHATASE R1 - Diethanolamine buffer (pH10.2)(.) R1 125 mmol/L Magnesium Chloride - -0.625mmol/L. ALKALINE PHOSPHATASE R2 - P-Nitro phenyl phosphate (.) R2 50 mmol /L 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
20	<ol style="list-style-type: none"> 1. Generic Name :Alkaline Washing Solution for TBA series of fully auto Analyzers (TBA wash solution 14) 2. Brand Name :Alkaline Washing Solution for TBA series of fully auto Analyzers (TBA wash solution 14) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch 14 is the alkaline detergent intended for cleansing and maintenance of reaction cuvette and aspiration probes of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series. 8. Material of Construction: Sodium Hydroxide (concentrated) Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
21	<ol style="list-style-type: none"> 1. Generic Name :Alpha 1 acid glycoprotein (AGP) 2. Brand Name :Alpha 1 acid glycoprotein (AGP) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Alpha 1 acid glycoprotein (AGP) in human serum 8. Material of Construction: Reagent 1 R1: PBS, Polyethylene glycol Reagent 2 R2: Polyclonal goat anti-human alpha 1 acid glycoprotein antibodies 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
22	<ol style="list-style-type: none"> 1. Generic Name :ALPHA 1-ACID GLYCOPROTEIN mispa i3 2. Brand Name :ALPHA 1-ACID GLYCOPROTEIN mispa i3 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Alpha1-Acid Glycoprotein in human serum. 8. Material of Construction: Reagent 1 R1: PBS, Polyethylene glycol Reagent 2 R2: Polyclonal goat anti-human alpha 1 acid glycoprotein antibodies 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

23	<ol style="list-style-type: none"> 1. Generic Name :ALPHA 1 -ANTI TRYPSIN (With Calibrator) 2. Brand Name :ALPHA 1 -ANTI TRYPSIN (With Calibrator) 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for the in vitro quantitative determination of a1-Antitrypsin (AAT) in human serum by nephelometric immunoassay. 8. Material of Construction: ALPHA 1 -ANTI TRYPSIN R1 - Glycine Buffer, ALPHA 1 -ANTI TRYPSIN R2 - Polyclonal goat anti-human 1 antitrypsin antibodies (stabilized), Reagent R3 - Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
24	<ol style="list-style-type: none"> 1. Generic Name :Alpha 1 antitrypsin i3(AAT I3) 2. Brand Name :Alpha 1 antitrypsin i3(AAT I3) 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Alpha 1 antitrypsin i3(AAT I3) in human serum 8. Material of Construction: Reagent 1 R1: Glycine Reagent 2 R2: Polyclonal goat anti-human a1 antitrypsin antibodies 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
25	<ol style="list-style-type: none"> 1. Generic Name :ALPHA 1-ACID GLYCOPROTEIN TEST KIT (With Calibrator) 2. Brand Name :ALPHA 1-ACID GLYCOPROTEIN TEST KIT (With Calibrator) 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Alpha1-Acid Glycoprotein in human serum. 8. Material of Construction: Alpha 1- Acid Glycoprotein (AGP) R1 - Phosphate buffered saline (pH7.43 Polyethylene glycol (60 g/L) Sodium azide (0.95 g/L), Alpha 1 Acid Glycoprotein (AGP) R2 - Phosphate buffered saline (pH 7.43 Polyclonal goat anti-human Alpha1-Acid Glycoprotein (variable) Sodium azide (0.95 g/L) and Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
26	<ol style="list-style-type: none"> 1. Generic Name :Alpha 1 Antitrypsin (AAT) 2. Brand Name :Alpha 1 Antitrypsin (AAT) 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Alpha 1 antitrypsin (AAT) in human serum 8. Material of Construction: Reagent 1 R1: Glycine Reagent 2 R2: Polyclonal goat anti-human a1 antitrypsin antibodies 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

27	<ol style="list-style-type: none"> 1. Generic Name :Alpha-2-macroglobulin - i3 2. Brand Name :Alpha-2-macroglobulin - i3 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The AGAPPE -Mispa i, Alpha-2-macroglobulin -i3test system is intended for in vitro quantitative determination of Alpha-2-macroglobulin -i3in serum. 8. Material of Construction: Reagent 1 R1: MES Buffer Reagent 2 R2 Polyclonal goat anti-human Alpha-2-macroglobulin -i3antibodies Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
28	<ol style="list-style-type: none"> 1. Generic Name :Alpha-2- macroglobulin 2. Brand Name :Alpha-2- macroglobulin 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The AGAPPE -Mispa i, alpha-2-macroglobulin test system is intended for in vitro quantitative determination of alpha-2-macroglobulin in serum. 8. Material of Construction: Reagent 1 R1: MES Buffer Reagent 2 R2 Polyclonal goat anti-human alpha-2-macroglobulin antibodies Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
29	<ol style="list-style-type: none"> 1. Generic Name :ALPHA AMLASE (AMYLASE) (SL) Kit 2. Brand Name :ALPHA AMLASE (AMYLASE) (SL) Kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of amylase in serum, plasma & urine. 8. Material of Construction: ALPHA AMLASE (AMYLASE) (SL) R1 - MES Buffer (pH6.0) 50 mmol/L CNPG3 2.27 mmol/L Calcium chloride 60 mmol/L Sodium chloride 70 mmol/L Activator 900 mmol/L 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
30	<ol style="list-style-type: none"> 1. Generic Name :ALPHA AMYLASE(AMYLASE)KIT 2. Brand Name :ALPHA AMYLASE(AMYLASE)KIT 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of amylase in human serum 8. Material of Construction: Reagent 1 R1: MES buffer CNPG3 Sodium chloride Calcium chloride 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

31	<ol style="list-style-type: none"> 1. Generic Name :Antithrombin III Reagent Kit 2. Brand Name :Antithrombin III Reagent Kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Antithrombin III in serum. 8. Material of Construction: Antithrombin III R1 - 20 mmol/L tris buffer/PEG, Tween 10 g/L, N3Na 0.95 g/L, Antithrombin III R2 - Goat anti-human ATHROM-III antibodies 50 mmol/L tris buffer sodium azide 0.95 g/L 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
32	<ol style="list-style-type: none"> 1. Generic Name :Apolipoprotein A1 Reagent Kit 2. Brand Name :Apolipoprotein A1 Reagent Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Apolipoprotein A1 in human serum 8. Material of Construction: Reagent 1 R1: Tris buffer Reagent 2 R2: Polyclonal goat anti-human Apo A1 Kit antiserum Reagent 3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
33	<ol style="list-style-type: none"> 1. Generic Name :Apo A1 (Mispa - i3) 2. Brand Name :Apo A1 (Mispa - i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Apolipoprotein A1 in human serum. 8. Material of Construction: Reagent 1 R1: Tris buffer Reagent 2 R2: Polyclonal goat anti-human Apo A1 (Mispa - i3) antiserum Reagent 3: Normal Saline. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
34	<ol style="list-style-type: none"> 1. Generic Name :Apo A1/Apo B CALIBRATOR 2. Brand Name :Apo A1/Apo B CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for the preparation of calibration curve for Apo A1 & Apo B estimation. 8. Material of Construction: APO A1/APO B CALIBRATOR 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

35	<ol style="list-style-type: none"> 1. Generic Name :Apo A1-B Dual Control 2. Brand Name :Apo A1-B Dual Control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Apo A1-B dual Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of Apo A and Apo B in human serum. 8. Material of Construction: Apo A1-B dual Control and Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
36	<ol style="list-style-type: none"> 1. Generic Name :Apo B (APOLIPOPROTEIN B) Reagent KIT 2. Brand Name :Apo B (APOLIPOPROTEIN B) Reagent KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Apo B (APOLIPOPROTEIN B)KIT in human serum 8. Material of Construction: Reagent 1 R1: Tris buffer Reagent 2 R2: Polyclonal goat anti-human Apo B (APOLIPOPROTEIN B)KIT antiserum Reagent 3: Normal Saline. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
37	<ol style="list-style-type: none"> 1. Generic Name :Apo B (Mispa -i3) 2. Brand Name :Apo B (Mispa -i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Apo B (Mispa -i3) in human serum 8. Material of Construction: Apo A1 R1 - Phosphate buffered saline (pH 7.43) Polyethylene glycol 60 g/L Detergent 0.1 % Sodium azide 0.95 g/L, Apo A1 R2 - Phosphate buffered saline (pH 7.43) Polyclonal goat anti-human APO-A1 (variable) Sodium azide 0.95 g/L and Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
38	<ol style="list-style-type: none"> 1. Generic Name :APOLIPOPROTEIN C II (APO C II) 2. Brand Name :APOLIPOPROTEIN C II (APO C II) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of APOLIPOPROTEIN C II in serum. 8. Material of Construction: APO C II R1 and APO C II R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

39	<ol style="list-style-type: none"> 1. Generic Name :Apolipoprotein C-III Reagent 2. Brand Name :Apolipoprotein C-III Reagent 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Apolipoprotein C-III in serum. 8. Material of Construction: Apolipoprotein C-III R1 and Apolipoprotein C-III R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
40	<ol style="list-style-type: none"> 1. Generic Name :ApoA1(APOLIPOPRTIEN A1 KIT)(With Calibrator) 2. Brand Name :ApoA1(APOLIPOPRTIEN A1 KIT)(With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Apo lipoprotein A1 (Apo-A1) in serum. 8. Material of Construction: Apo A1 R1 - Phosphate buffered saline (pH 7.43) Polyethylene glycol 60 g/L Detergent 0.1 % Sodium azide 0.95 g/L, Apo A1 R2 - Phosphate buffered saline (pH 7.43) Polyclonal goat anti-human APO-A1 (variable) Sodium azide 0.95 g/L and Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
41	<ol style="list-style-type: none"> 1. Generic Name :Apolipoprotein E Reagent 2. Brand Name :Apolipoprotein E Reagent 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Apolipoprotein E in serum. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) antigens 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
42	<ol style="list-style-type: none"> 1. Generic Name :ASO CALIBRATOR 2. Brand Name :ASO CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for the preparation of calibration curve for ASO estimation. 8. Material of Construction: Anti Streptolysin – O (ASO) with physiological saline containing 1 % (w/v) bovine serum albumin under rigid quality control standards 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

43	<ol style="list-style-type: none"> 1. Generic Name :ASO cartridge Mispa i3 2. Brand Name :ASO cartridge Mispa i3 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of ASO in human serum 8. Material of Construction: ASO Reagents R1: Glycine buffer solution R2: ASO latex suspension particles coated with streptolysin-O 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
44	<ol style="list-style-type: none"> 1. Generic Name :ASO LATEX 2. Brand Name :ASO LATEX 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of ASO in human serum. 8. Material of Construction: R1 - Glycine buffer Solution R2 -ASO Latex suspension particles coated with Streptolysin- O and Dilution buffer 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
45	<ol style="list-style-type: none"> 1. Generic Name :ASO LATEX SLIDE KIT (ASO) 2. Brand Name :ASO LATEX SLIDE KIT (ASO) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro qualitative & semi quantitative determination of Anti Streptolysin O (ASO) in serum. 8. Material of Construction: Suspension of polystyrene particles coated with streptolysin-O. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
46	<ol style="list-style-type: none"> 1. Generic Name :ASO LEIT WITH CALIBRATOR 2. Brand Name :ASO LEIT WITH CALIBRATOR 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro qualitative & semi quantitative determination of Anti Streptolysin O (ASO) in serum. 8. Material of Construction: Suspension of polystyrene particles coated with streptolysin-O. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

47	<ol style="list-style-type: none"> 1. Generic Name :ASO TURBILATEX KIT (ASO)(With Calibrator) 2. Brand Name :ASO TURBILATEX KIT (ASO)(With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Anti Streptolysin-O (ASO) in human serum. 8. Material of Construction: ASO R1 : Glycine buffer solution ASO R2: ASO Latex suspension particles coated with Streptolysin - O and ASO Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
48	<ol style="list-style-type: none"> 1. Generic Name :BASE WASHING SOLUTION (WASHING SOLUTION(AI)) 2. Brand Name :BASE WASHING SOLUTION (WASHING SOLUTION(AI)) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Alkaline washing detergent intended for cleansing and maintenance of reaction cuvette and aspiration probes of BiOLis 24i automated clinical analyzer. 8. Material of Construction: Alkaline solution (concentrated) Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
49	<ol style="list-style-type: none"> 1. Generic Name :BATH ADDITIVE 2. Brand Name :BATH ADDITIVE 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch R is intended as bath additive for the isothermal bath of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series. 8. Material of Construction: Sodium Chloride, Surfactant, Sodium acetate 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
50	<ol style="list-style-type: none"> 1. Generic Name :BATH ADDITIVE BIANCH R 2. Brand Name :BATH ADDITIVE BIANCH R 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch R is intended as bath additive for the isothermal bath of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series. 8. Material of Construction: Sodium Chloride, Surfactant, Sodium acetate 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

51	<p>1. Generic Name :Bath Additive for TBA series of fully auto analyzers (TBA Wash Solution R)</p> <p>2. Brand Name :Bath Additive for TBA series of fully auto analyzers (TBA Wash Solution R)</p> <p>3. Notified Category :Other than above substancesCleansing solution</p> <p>4. Class of Medical Device :Class A</p> <p>5. Shelf life :3 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Bianch R is intended as bath additive for the isothermal bath of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series.</p> <p>8. Material of Construction: Sodium Chloride, Surfactant, Sodium acetate</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
52	<p>1. Generic Name :Bilirubin Direct Kit</p> <p>2. Brand Name :Bilirubin Direct Kit</p> <p>3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This reagent is intended for in vitro quantitative determination of Bilirubin in serum or plasma.</p> <p>8. Material of Construction: Direct Bilirubin Reagent, BILIRUBIN direct ACTIVATOR, Bilirubin Artificial standard</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
53	<p>1. Generic Name :Bilirubin Total and Direct kit-Combination kit(Bilirubin Total and Direct TAB) and Direct kit-Combination kit</p> <p>2. Brand Name :Bilirubin Total and Direct kit-Combination kit(Bilirubin Total and Direct TAB) and Direct kit-Combination kit(Bilirubin Total and Direct kit-Combination kit(Bilirubin Total and Direct TAB) and Direct TAB)</p> <p>3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This reagent is intended for in vitro quantitative determination of Bilirubin in serum or plasma.</p> <p>8. Material of Construction: Direct Bilirubin Reagent, BILIRUBIN direct ACTIVATOR, Bilirubin Artificial standard</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
54	<p>1. Generic Name :Bilirubin total Kit Kit</p> <p>2. Brand Name :Bilirubin total Kit Kit</p> <p>3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This reagent is intended for in vitro quantitative determination of Bilirubin in serum or plasma.</p> <p>8. Material of Construction: Total Bilirubin Reagent, BILIRUBIN direct ACTIVATOR, Bilirubin Artificial standard</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>

55	<ol style="list-style-type: none"> 1. Generic Name :Bilirubin total (TAB kit) 2. Brand Name :Bilirubin total (TAB kit) 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Bilirubin in serum or plasma. 8. Material of Construction: BILIRUBIN TOTAL REAGENT, BILIRUBIN TOTAL ACTIVATOR 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
56	<ol style="list-style-type: none"> 1. Generic Name :Calcium Kit 2. Brand Name :Calcium Kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Calcium in serum,plasma & urine. 8. Material of Construction: CALCIUM DYE R2, CALCIUM BASE R1, CALCIUM STANDARD 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
57	<ol style="list-style-type: none"> 1. Generic Name :calcuim (arsenazo) kit 2. Brand Name :calcuim (arsenazo) kit 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Calcium in serum, plasma & urine. 8. Material of Construction: CALCIUM ARSENAZO REAGENT, CALCIUM ARSENAZO STANDARD 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
58	<ol style="list-style-type: none"> 1. Generic Name :Carbon Dioxide (CO2) Calibrator 2. Brand Name :Carbon Dioxide (CO2) Calibrator 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for Carbon Dioxide estimation. 8. Material of Construction: Carbon Dioxide Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

59	<ol style="list-style-type: none"> 1. Generic Name :Carbon Dioxide (CO2) Enzymatic Assay 2. Brand Name :Carbon Dioxide (CO2) Enzymatic Assay 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Carbon dioxide in serum. 8. Material of Construction: CARBON DIOXIDE R1, CARBON DIOXIDE R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
60	<ol style="list-style-type: none"> 1. Generic Name :Carbon Dioxide (CO2) Control 2. Brand Name :Carbon Dioxide (CO2) Control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Carbon Dioxide Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of Carbon Dioxide in human serum. 8. Material of Construction: CO2 control, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
61	<ol style="list-style-type: none"> 1. Generic Name :Ceruleplasmin (Mispa-i3) 2. Brand Name :Ceruleplasmin (Mispa-i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Ceruloplasmin (Mispa-i3) in human serum 8. Material of Construction: Reagent 1 R1: phosphate buffered saline with PEG Reagent 2 R2: Polyclonal goat anti-human Ceruloplasmin (Mispa-i3) antibodies (stabilized) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
62	<ol style="list-style-type: none"> 1. Generic Name :Ceruleplasmin Kit 2. Brand Name :Ceruleplasmin Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of ceruloplasmin in human serum 8. Material of Construction: Reagent 1 R1: phosphate buffered saline with PEG Reagent 2 R2: Polyclonal goat anti-human Ceruloplasmin antibodies (stabilized) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

63	<ol style="list-style-type: none"> 1. Generic Name :CERULOPLASMIN KIT (With Calibrator) 2. Brand Name :CERULOPLASMIN KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Ceruloplasmin in serum 8. Material of Construction: Ceruloplasmin - R1, Ceruloplasmin - R2, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
64	<ol style="list-style-type: none"> 1. Generic Name :CHLORIDE KIT 2. Brand Name :CHLORIDE KIT 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Chloride in Serum, plasma & urine. 8. Material of Construction: CHLORIDE REAGENT, CHLORIDE STANDARD 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
65	<ol style="list-style-type: none"> 1. Generic Name :CHOLESTEROL (SL) KIT 2. Brand Name :CHOLESTEROL (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of cholesterol in human serum. 8. Material of Construction: Pipes buffer, PhenolSodium cholate, 4-aminoantipyrine, Cholesterol esterase, Cholesterol oxidase, Peroxidase 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
66	<ol style="list-style-type: none"> 1. Generic Name :CHOLESTEROL KIT 2. Brand Name :CHOLESTEROL KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Cholesterol in serum or plasma. 8. Material of Construction: Cholesterol R1, Cholesterol R2, Cholesterol Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

67	<ol style="list-style-type: none"> 1. Generic Name :CK MB LATEX BASED REAGENT KIT 2. Brand Name :CK MB LATEX BASED REAGENT KIT 3. Notified Category :Other than above substancesClinical Chemistry Reagent Kit 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of CK-MB in serum. 8. Material of Construction: CK MB Latex Based Reagent R1, CK MB Latex Based Reagent R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
68	<ol style="list-style-type: none"> 1. Generic Name :CK-MB (SL) CREATNE KINASE MB KIT(SL) 2. Brand Name :CK-MB (SL) CREATNE KINASE MB KIT(SL) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of CK-MB (SL) CREATNE KINASE MB KIT(SL) in human serum 8. Material of Construction: Reagent 1 R1: Imidazole, D-Glucose, N-Acetyl L-Cysteine, Magnesium acetate, NADP, EDTA Hexokinase Anti -human polyclonal CK-M antibody Creatine phosphate ADP 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
69	<ol style="list-style-type: none"> 1. Generic Name :CK-MB Calibration Test Kit 2. Brand Name :CK-MB Calibration Test Kit 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :CK-MB Calibrator is intended for the calibration of manual and automated analytical procedures. 8. Material of Construction: CK-MB Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
70	<ol style="list-style-type: none"> 1. Generic Name :CK-MB KIT (CREATININE KINASE MB KIT) (With Calibrator) 2. Brand Name :CK-MB KIT (CREATININE KINASE MB KIT) (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of CK-MB in human serum/plasma. 8. Material of Construction: CK-MB R1, CK-MB R2, CK-MB Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

71	<ol style="list-style-type: none"> 1. Generic Name :CK-MB KIT(CREATINE KINASE MB KIT) 2. Brand Name :CK-MB KIT(CREATINE KINASE MB KIT) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of CK-MB KIT(CREATINE KINASE MB KIT) in human serum 8. Material of Construction: Reagent 1 R1: Imidazole, D-Glucose, N-Acetyl L-Cysteine, Magnesium acetate, NADP, EDTA Hexokinase Document NO: ADL/DOC/DMF/CKMB /2018/R00 Date: 05/11/2018 Page 8 of 62 Anti -human polyclonal CK-M antibody Creatine phosphate ADP AMP Di adenosine penta phosphate) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
72	<ol style="list-style-type: none"> 1. Generic Name :CK-MB/cTnl/Myo FAST TEST KIT 2. Brand Name :CK-MB/cTnl/Myo FAST TEST KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :CK-MB/cTnl/Myo Fast Test Kit (Immunofluorescence Assay) applies fluorescence immunochromatography to detect CK-MB/cTnl/Myo in serum, plasma or whole blood samples quantitatively. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS). 8. Material of Construction: Foil Bag, Manual, SD Card, Phosphate buffered saline Protein Detergent Preservative Stabilizer 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
73	<ol style="list-style-type: none"> 1. Generic Name :CK-NAC (CREATINEKINASE KIT (SL)) 2. Brand Name :CK-NAC (CREATINEKINASE KIT (SL)) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of CK-NAC in human serum 8. Material of Construction: C K-NAC Reagent Imidazole buffer D-glucose N-acetyl-L-cysteine Magnesium acetate NADP EDTA Hexokinase Creatine phosphate 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
74	<ol style="list-style-type: none"> 1. Generic Name :CK-NAC TEST KIT 2. Brand Name :CK-NAC KIT (CREATININE KINASE NAC KIT) , 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of CK-NAC in human serum/plasma. 8. Material of Construction: CK-NAC R1, CK-NAC R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

75	<ol style="list-style-type: none"> 1. Generic Name :cleaner for 5-part diff. hematology analyzer (diff. C5) 2. Brand Name :cleaner for 5-part diff. hematology analyzer (diff. C5) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Sheath Solution is intended for cleaning the tubing's of Mispa Count-5 part Differential Hematology Analyzer. It is an azide free filtered solution. 8. Material of Construction: Boric acid, Sodium chloride, Sodium sulphate, EDTA, CWT 3030, TRITON 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
76	<ol style="list-style-type: none"> 1. Generic Name :Cleaning solution for 5- part hematology Differential Analyzer (cleaner DS5000) 2. Brand Name :Cleaning solution for 5- part hematology Differential Analyzer (cleaner DS5000) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Cleaning solution is intended for cleaning the tubing's of Mispa Count plus 5 part Differential Hematology Analyzer. It is an azide free filtered solution. 8. Material of Construction: Sodium chloride, Sodium sulphate anhydrous, Buffering agents, Nonionic surfactant, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
77	<ol style="list-style-type: none"> 1. Generic Name :CLINICAL CHEMISTRY ANALYZER CELL WASH 2. Brand Name :CLINICAL CHEMISTRY ANALYZER CELL WASH 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Acid wash detergent is intended for cleansing and maintenance of reaction cuvettes and aspiration probes of BiOLis 24i automated clinical analyzer. 8. Material of Construction: Cell Wash 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
78	<ol style="list-style-type: none"> 1. Generic Name :CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 1 2. Brand Name :CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 1 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :CLINICAL CHEMISTRY CONTROL LEVEL 1 is an assayed human serum used for quality control checking of clinical chemistry assays suitable for manual procedure and automated analyzers. 8. Material of Construction: CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 1 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

79	<ol style="list-style-type: none"> 1. Generic Name :CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 2 2. Brand Name :CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 2 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :CLINICAL CHEMISTRY CONTROL LEVEL 2 is an assayed human serum used for quality control checking of clinical chemistry assays suitable for manual procedure and automated analyzers. 8. Material of Construction: CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
80	<ol style="list-style-type: none"> 1. Generic Name :CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 3 2. Brand Name :CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 3 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :CLINICAL CHEMISTRY CONTROL LEVEL 3 is an assayed human serum used for quality control checking of clinical chemistry assays suitable for manual procedure and automated analyzers. 8. Material of Construction: CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 3 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
81	<ol style="list-style-type: none"> 1. Generic Name :CLINICAL CHEMISTRY MULTICALIBRATOR 2. Brand Name :CLINICAL CHEMISTRY MULTICALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Multicalibrator is a calibration serum intended for calibration of clinical chemistry assays suitable for manual procedure and automated analyzers. 8. Material of Construction: Multicalibrator Lyophilized human serum with additives Bacteriostatic agents and stabilizers. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
82	<ol style="list-style-type: none"> 1. Generic Name :Complement 3 (C3) (Mispa-i3) 2. Brand Name :Complement 3 (C3) (Mispa-i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Complement Component COMPLEMENT 3 (C3) (MISPA-I3) (COMPLEMENT 3 (C3) (MISPA-I3)) in human serum 8. Material of Construction: PBS Polyethylene glycol, Polyclonal goat anti-human C3 antibodies, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

83	<ol style="list-style-type: none"> 1. Generic Name :COMPLEMENT 4 (C4) (MISPA -I3) 2. Brand Name :COMPLEMENT 4 (C4) (MISPA -I3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Complement Component COMPLEMENT 4 (C4) (MISPA -I3) (COMPLEMENT 4 (C4) (MISPA -I3)) in human serum 8. Material of Construction: Tris Buffer, Polyclonal anti-human, antibody 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
84	<ol style="list-style-type: none"> 1. Generic Name :COMPLEMENT C3 (C3) 2. Brand Name :COMPLEMENT C3 (C3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Complement Component C3 (C3) in human serum 8. Material of Construction: PBS Polyethelene glycol, Polyclonal goat anti-human C3 antibodies, Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
85	<ol style="list-style-type: none"> 1. Generic Name :COMPLIMENT C3 (C3) (With Calibrator) 2. Brand Name :COMPLIMENT C3 (C3) (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of complement C3 in human serum. 8. Material of Construction: Phosphate buffered saline, Polyethylene glycol, Sodium azide, Phosphate buffered saline, Polyclonal goat anti-human C3C (variable) Sodium azide, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
86	<ol style="list-style-type: none"> 1. Generic Name :Component C4 (C4) 2. Brand Name :Component C4 (C4) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Complement Component C4 (C4) in human serum 8. Material of Construction: Tris Buffer, Polyclonal anti-human C4 antibody 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

87	<ol style="list-style-type: none"> 1. Generic Name :COMPLIMENT C4(C4) (With Calibrator) 2. Brand Name :COMPLIMENT C4(C4) (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of complement C4 in human serum. 8. Material of Construction: Phosphate buffered saline, Polyethylene glycol, Sodium azide, Phosphate buffered saline, Polyclonal goat anti-human C4C (variable) Sodium azide, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
88	<ol style="list-style-type: none"> 1. Generic Name :COUNT C3 CLEANING SOLUTION FOR 3-PART HEMATOLOGY ANALYZER 2. Brand Name :COUNT C3 CLEANING SOLUTION FOR 3-PART HEMATOLOGY ANALYZER 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Count C3 is intended for cleaning the tubing's of Mispa Count-3 part Differential Hematology Analyzer. It is an azide free filtered solution. 8. Material of Construction: Sodium chloride, Sodium sulphate anhydrous, Buffering agents, Nonionic surfactant, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
89	<ol style="list-style-type: none"> 1. Generic Name :COUNT D3 REAGENT (DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER FOR MISPA COUNT) 2. Brand Name :COUNT D3 REAGENT (DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER FOR MISPA COUNT) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :COUNT D3 is intended for diluent the tubing's of Mispa Count-3 part Differential Hematology Analyzer. It is an azide free filtered solution. 8. Material of Construction: Sodium chloride, Sodium sulphate anhydrous, Buffering agents, Nonionic surfactant, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

90	<p>1. Generic Name :COUNT D3 DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER</p> <p>2. Brand Name :COUNT D3 DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER</p> <p>3. Notified Category :Other than above substancesCleansing solution</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :COUNT D3 is intended for diluent the tubing's of Mispa Count-3 part Differential Hematology Analyzer. It is an azide free filtered solution.</p> <p>8. Material of Construction: Sodium chloride, Sodium sulphate anhydrous, Buffering agents, Nonionic surfactant, Anti-fungal& Anti-bacterial agent</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
91	<p>1. Generic Name :COUNT L3 LYSING REAGENT FOR 3 - PART HEMATOLOGY ANALYZER</p> <p>2. Brand Name :COUNT L3 LYSING REAGENT FOR 3 - PART HEMATOLOGY ANALYZER</p> <p>3. Notified Category :Other than above substancesHematology Analyzer</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diff L3 is intended for lysing of cells for WBC Count, and Hemoglobin measurement in Mispa Count plus -3 part Differential Hematology Analyzer.</p> <p>8. Material of Construction: Dodecyl Trimethyl Ammonium Chloride, Dodecyl Trimethyl Ammonium Bromide, Hexamine, IPA,</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
92	<p>1. Generic Name :COUNT L3 Reagent (Lyse for 3- Part hematology analyzer for Mispa count)</p> <p>2. Brand Name :COUNT L3 Reagent (Lyse for 3- Part hematology analyzer for Mispa count)</p> <p>3. Notified Category :Other than above substancesHematology Analyzer</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diff L5 is intended for lysing of cells for WBC Count, WBC differentials and Hemoglobin measurement in Mispa Count plus -5 part Differential Hematology Analyzer.</p> <p>8. Material of Construction: Dodecyl Trimethyl Ammonium Chloride, Dodecyl Trimethyl Ammonium Bromide, Hexamine, IPA,</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
93	<p>1. Generic Name :Enzymatic creatinine</p> <p>2. Brand Name :Enzymatic creatinine</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :24 Months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Enzymatic creatinine in human serum</p> <p>8. Material of Construction: Creatinase, Sarcosine oxidase, TOOS, Creatininase, Peroxidase, 4-AA, Enzymatic creatinine Standard</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>

94	<ol style="list-style-type: none"> 1. Generic Name :CREATININE KIT 2. Brand Name :CREATININE KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Creatinine in serum plasma and urine. 8. Material of Construction: Creatinine Base Reagent (R1), Creatinine Dye Reagent (R2), Creatinine Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
95	<ol style="list-style-type: none"> 1. Generic Name :CUVETTE CLEANING SOLUTION BIANCH C 2. Brand Name :CUVETTE CLEANING SOLUTION BIANCH C 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch C is intended for cleansing of reaction cuvette in startup of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series. Bianch C is also used as the detergent for minimizing carryover. 8. Material of Construction: Sodium Acetate, Sodium Carbonate, Sodium Hypochlorite solution, Stabilizer, Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
96	<ol style="list-style-type: none"> 1. Generic Name :CUVETTE CLEANING SOLUTION 2. Brand Name :CUVETTE CLEANING SOLUTION 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Bianch C is intended for cleansing of reaction cuvette in startup of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series. Bianch C is also used as the detergent for minimizing carryover. 8. Material of Construction: Sodium Acetate, Sodium Carbonate, Sodium Hypochlorite solution, Stabilizer, Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

97	<p>1. Generic Name :Cuvette wash solution for TBA series of fully auto analyzers (TBA Wash solution C)</p> <p>2. Brand Name :Cuvette wash solution for TBA series of fully auto analyzers (TBA Wash solution C)</p> <p>3. Notified Category :Other than above substancesCleansing solution</p> <p>4. Class of Medical Device :Class A</p> <p>5. Shelf life :3 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Bianch C is intended for cleansing of reaction cuvette in startup of TOSHIBA (TBA) fully automated random access clinical chemistry analyzer series. Bianch C is also used as the detergent for minimizing carryover.</p> <p>8. Material of Construction: Sodium Acetate, Sodium Carbonate, Sodium Hypochlorite solution, Stabilizer, Preservative</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
98	<p>1. Generic Name :Cystaitn-C Cartridge(Mispa -i3)</p> <p>2. Brand Name :Cystaitn-C Cartridge(Mispa -i3)</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :12 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Cystatin C in human serum</p> <p>8. Material of Construction: Reagent 1 R1: Tris buffer solution Reagent 2 R2: Synthesized polystyrene latex particles coated with polyclonal cystatin-C antibody (rabbit)</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
99	<p>1. Generic Name :CYSTATIN-C</p> <p>2. Brand Name :CYSTATIN-C</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :12 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Cystatin C in human serum</p> <p>8. Material of Construction: Reagent 1 R1: Tris buffer Reagent 2 R2: Synthesized polystyrene Latex particle coated with polyclonal anti Cystatin-C antibody.</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
100	<p>1. Generic Name :Cystatin C Calibrator</p> <p>2. Brand Name :Cystatin C Calibrator</p> <p>3. Notified Category :Other than above substancesCalibrators/Controls</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This calibrator is intended for the preparation of calibration curve for Cystatin C estimation.</p> <p>8. Material of Construction: human plasma with saline.</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>

101	<ol style="list-style-type: none"> 1. Generic Name :Cystatin C Control 2. Brand Name :Cystatin C Control 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Cystatin C Control is an assayed quality control intended for monitoring the Accuracy and precision of Cystatin C assay. 8. Material of Construction: Cystatin C Control 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
102	<ol style="list-style-type: none"> 1. Generic Name :CYSTATIN C KIT (With Calibrator) 2. Brand Name :CYSTATIN C KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Cystatin C in human serum 8. Material of Construction: Cystatin C R1, Cystatin C R2, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
103	<ol style="list-style-type: none"> 1. Generic Name :Cystatin Control 2. Brand Name :Cystatin Control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Cystatin Control is an assayed quality control intended for monitoring the Accuracy and precision of Cystatin C assay. 8. Material of Construction: Cystatin Control 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
104	<ol style="list-style-type: none"> 1. Generic Name :Diagnostic Kit for Copper 2. Brand Name :Diagnostic Kit for Copper 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Copper in serum or plasma. 8. Material of Construction: Copper Reagent (R1), Copper Reagent (R2), Copper Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

105	<ol style="list-style-type: none"> 1. Generic Name :Diluent (Diluent solution for 3-part hematology analyzer) 2. Brand Name :Diluent (Diluent solution for 3-part hematology analyzer) 3. Notified Category :Other than above substancesDiluent 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diluent is intended for counting and sizing of blood cells in Mindray- 3 part Differential Hematology Analyzers of BC Series. It is an azide free filtered isotonic solution. 8. Material of Construction: Sodium chloride, Sodium sulphate anhydrous, Buffering agents, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
106	<ol style="list-style-type: none"> 1. Generic Name :Diluent Solution for 5-Part Heamatology analyzer 2. Brand Name :Diluent Solution for 5-Part Heamatology analyzer 3. Notified Category :Other than above substancesDiluent 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diff D5 is intended for counting and sizing of blood cells in Mispa Count Plus 5 - part Differential Hematology Analyzer. It is an azide free filtered isotonic solution. 8. Material of Construction: Boric acid, Sodium chloride, Sodium sulphate, EDTA, CWT 3030 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
107	<ol style="list-style-type: none"> 1. Generic Name :DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER 2. Brand Name :DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER 3. Notified Category :Other than above substancesDiluent 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diff D5 is intended for counting and sizing of blood cells in Mispa Count Plus 5 - part Differential Hematology Analyzer. It is an azide free filtered isotonic solution. 8. Material of Construction: Boric acid, Sodium chloride, Sodium sulphate, EDTA, imidazole, CWT 3030 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
108	<ol style="list-style-type: none"> 1. Generic Name :Diluent Solution for 5-Part Heamatology analyzer (Diluent DS5000) 2. Brand Name :Diluent Solution for 5-Part Heamatology analyzer (Diluent DS5000) 3. Notified Category :Other than above substancesDiluent 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diff D5 is intended for counting and sizing of blood cells in Mispa Count Plus 5 - part Differential Hematology Analyzer. It is an azide free filtered isotonic solution. 8. Material of Construction: Boric acid, Sodium chloride, Sodium sulphate, EDTA, imidazole, CWT 3030 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

109	<ol style="list-style-type: none"> 1. Generic Name :Enzymatic Lithium 2. Brand Name :Enzymatic Lithium 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the determination of lithium in human serum. 8. Material of Construction: Enzymatic Lithium R1, Enzymatic Lithium R2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
110	<ol style="list-style-type: none"> 1. Generic Name :Enzymatic Lithium calibrator set 2. Brand Name :Enzymatic Lithium calibrator set 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the calibration of lithium estimation in human serum. 8. Material of Construction: Enzymatic Lithium calibrator set R1-level 1 Enzymatic Lithium calibrator set R1-level 2 Enzymatic Lithium calibrator set R1-level 3 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
11 1	<ol style="list-style-type: none"> 1. Generic Name :ENZYMATIC LITHIUM CONTROL SET 2. Brand Name :ENZYMATIC LITHIUM CONTROL SET 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the calibration of lithium estimation in human serum. 8. Material of Construction: Enzymatic Lithium control set R1-level 1 Enzymatic Lithium control set R1-level 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
112	<ol style="list-style-type: none"> 1. Generic Name :ENZYMATIC POTASSIUM REAGENT KIT 2. Brand Name :ENZYMATIC POTASSIUM REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the determination of potassium in human serum. 8. Material of Construction: Reagent 1 (R1) which contains LDH, Substrate, NADH analog, azide and stabilizers. Reagent R2 consists of pyruvate kinase, azide and stabilizers. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

113	<ol style="list-style-type: none"> 1. Generic Name :Enzymatic Potassium calibrator 2. Brand Name :Enzymatic Potassium calibrator 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the quality control of IVD determination of potassium in human serum through enzymatic method. 8. Material of Construction: potassium standards 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
114	<ol style="list-style-type: none"> 1. Generic Name :ENZYMATIC POTASSIUM CONTROL KIT 2. Brand Name :ENZYMATIC POTASSIUM CONTROL KIT 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the quality control of ivd determination of potassium in human serum through enzymatic method. 8. Material of Construction: potassium standards 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
115	<ol style="list-style-type: none"> 1. Generic Name :ENZYMATIC SODIUM REAGENT KIT 2. Brand Name :ENZYMATIC SODIUM REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the determination of sodium in human serum. 8. Material of Construction: Reagent 1 (R1) which contains Goods buffer, cryptand, - D-galactosidase, isothiazoline. Reagent R2 consists of o-nitrophenyl -D- galactopyranose, Goods buffer, isothiazoline. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
116	<ol style="list-style-type: none"> 1. Generic Name :ENZYMATIC SODIUM CALIBRATOR KIT 2. Brand Name :ENZYMATIC SODIUM CALIBRATOR KIT 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the quality control in the determination of sodium in human serum. 8. Material of Construction: Reagent 1 (R1) which contains Goods buffer, cryptand, - Dgalactosidase, isothiazoline. Reagent R2 consists of o-nitrophenyl -D- galactopyranose, Goods buffer, isothiazoline. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

11 7	<ol style="list-style-type: none"> 1. Generic Name :ENZYMATIC SODIUM CONTROL KIT 2. Brand Name :ENZYMATIC SODIUM CONTROL KIT 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the quality control in the determination of sodium in human serum. 8. Material of Construction: Reagent 1 (R1) which contains Goods buffer, cryptand, - Dgalactosidase, isothiazoline. Reagent R2 consists of o-nitrophenyl -D- galactopyranose, Goods buffer, isothiazoline. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
118	<ol style="list-style-type: none"> 1. Generic Name :EZ Cleaner for 3-Part hematology analyzer, EZ Cleaner 2. Brand Name :EZ Cleaner for 3-Part hematology analyzer, EZ Cleaner 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :EZ cleaner is intended for daily cleaning of MINDRAY- 3 part Differential Hematology Analyzers of BC Series. 8. Material of Construction: Proteolytic enzyme, Substrate, Sodium chloride, Buffering agents, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
119	<ol style="list-style-type: none"> 1. Generic Name :FERRITIN KIT 2. Brand Name :FERRITIN KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of in Ferritin human serum 8. Material of Construction: Reagent 1 R1: Glycine buffer Reagent 2 R2: Suspension of latex particle bound to anti-ferritin antibodies 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
120	<ol style="list-style-type: none"> 1. Generic Name :FERRITIN CALIBRATOR 2. Brand Name :FERRITIN CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Ferritin Calibrator is intended for the preparation of calibration curve for Ferritin estimation. 8. Material of Construction: Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

121	<ol style="list-style-type: none"> 1. Generic Name :Ferritin Cartridge (Mispa i3) 2. Brand Name :Ferritin Cartridge (Mispa i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of in Ferritin human serum 8. Material of Construction: Reagent 1 R1: Glycine buffer Reagent 2 R2: Suspension of latex particle bound to anti-ferritin antibodies 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
122	<ol style="list-style-type: none"> 1. Generic Name :FERRITIN CONTROL 2. Brand Name :FERRITIN CONTROL 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Ferritin Control is an assayed quality control intended for monitoring the precision of laboratory testing procedures. 8. Material of Construction: Control 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
123	<ol style="list-style-type: none"> 1. Generic Name :FERRITIN TURBILATEX KIT (WITH CALIBRATOR) 2. Brand Name :FERRITIN TURBILATEX KIT (WITH CALIBRATOR) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :The reagent is intended for in vitro quantitative determination of Ferritin in serum 8. Material of Construction: Ferritin - R1: Glycine buffer, Ferritin - R2: Suspension of latex particle bound to anti-ferritin antibodies, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
124	<ol style="list-style-type: none"> 1. Generic Name :GAMMA GT Kit 2. Brand Name :GAMMA GT Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of GAMMA GT , in serum, plasma & urine. 8. Material of Construction: GAMMA GT , R1; Tris buffer, Glycylglycine, GAMMA GT , R2: GLUPA-C 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

125	<ol style="list-style-type: none"> 1. Generic Name :GAMMA GT S.L Kit 2. Brand Name :GAMMA GT S.L Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of GAMMA GT S.L in serum, plasma & urine. 8. Material of Construction: GAMMA GT S.L , R1; Tris buffer, Glycylglycine, GAMMA GT S.L R2: GLUPA-C 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
126	<ol style="list-style-type: none"> 1. Generic Name :GENERAL PURPOSE DILUENT FOR HEMATOLOGY ANALYZER 2. Brand Name :GENERAL PURPOSE DILUENT FOR HEMATOLOGY ANALYZER 3. Notified Category :Other than above substancesDiluent 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diluent is intended for counting and sizing of blood cells in Mindray- 3 part Differential Hematology Analyzers of BC Series. It is an azide free filtered isotonic solution. 8. Material of Construction: Sodium chloride, Sodium sulphate anhydrous, Buffering agents, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
127	<ol style="list-style-type: none"> 1. Generic Name :GLUCOSE (SL) Kit 2. Brand Name :GLUCOSE (SL) Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Glucose in human serum 8. Material of Construction: Tris buffer Phenol Radiation safety The Ferritin reagent does not emit any radiation Disposal Dilute with Hypochlorite solution and discard Storage during transit 2-8oC Accelerated stability (15 days at 37oC and 45oC) Meets specifications Real time stability at 2-8°C Stable at 2-80C for 24 months Document NO: ADL/DOC/DMF/GLCSE SL/2018/R00 Date: 09/11/2018 Page 8 of 69 Glucose oxidase 4-amino antipyrine Glucose Standard Glucose 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
128	<ol style="list-style-type: none"> 1. Generic Name :Glucose Hexokinase 2. Brand Name :Glucose Hexokinase 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Glucose in serum. 8. Material of Construction: Pipes buffer, Hexokinase 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

129	<ol style="list-style-type: none"> 1. Generic Name :GLUCOSE KIT 2. Brand Name :GLUCOSE KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Glucose in serum, plasma & CSF. 8. Material of Construction: Glucose R1: Phosphate buffer, Phenol, Glucose R2: Glucose Oxidase, Peroxidase, 4-Aminoantipyrine, Glucose Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
130	<ol style="list-style-type: none"> 1. Generic Name :GLUCOSE STRIPS 2. Brand Name :GLUCOSE STRIPS 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Urine test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders 8. Material of Construction: Glucose oxidase, Peroxidase, Glucose Buffer, Non-Reactive Ingredients 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
131	<ol style="list-style-type: none"> 1. Generic Name :Haptoglobin Test Kit 2. Brand Name :Haptoglobin Test Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Haptoglobin in human serum 8. Material of Construction: Reagent 1 R1: Tris Buffer Reagent 2 R2: Polyclonal goat anti-human Haptoglobin antibodies Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
132	<ol style="list-style-type: none"> 1. Generic Name :Haptoglobin (Mispa-i3) 2. Brand Name :Haptoglobin (Mispa-i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Haptoglobin (Mispa-i3) in human serum 8. Material of Construction: Reagent 1 R1: Tris Buffer Reagent 2 R2: Polyclonal goat anti-human Haptoglobin (Mispa-i3) antibodies Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

133	<ol style="list-style-type: none"> 1. Generic Name :HbA1C kit 2. Brand Name :HbA1C kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Glucose in human serum 8. Material of Construction: HbA1c R1 - Latex, Glycine buffer. HbA1c R2 - Glycine buffer 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
134	<ol style="list-style-type: none"> 1. Generic Name :HbA1c Cartridge Mispa i3 2. Brand Name :HbA1c Cartridge Mispa i3 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Glucose in human serum 8. Material of Construction: Glycine latex buffer, Glycine buffer Mouse antihuman HbA1c monoclonal antibody Goat anti-mouse IgG Polyclonal antibody Stabilizers, Haemolysing reagent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
135	<ol style="list-style-type: none"> 1. Generic Name :HbA1c CONTROL LEVEL 1&2 2. Brand Name :HbA1c CONTROL LEVEL 1&2 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :HbA1c control is an assayed quality control intended for monitoring the precision of laboratory testing procedures. 8. Material of Construction: HbA1c Control Level 1, HbA1c Control Level 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
136	<ol style="list-style-type: none"> 1. Generic Name :HbA1c CONTROL KIT 2. Brand Name :HbA1c CONTROL KIT 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :HbA1c control is an assayed quality control intended for monitoring the precision of laboratory testing procedures. 8. Material of Construction: HbA1c Control Level 1, HbA1c Control Level 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

137	<ol style="list-style-type: none"> 1. Generic Name :HbA1c DIRECT KIT 2. Brand Name :HbA1c DIRECT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of % HbA1c in human blood. 8. Material of Construction: HbA1c Direct R1: Latex, HbA1c Direct R2: Anti-human HbA1c mouse monoclonal antibody Anti-mouse IgG goat antibody, HbA1c R3: Haemolysis Reagent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
138	<ol style="list-style-type: none"> 1. Generic Name :HbA1c DIRECT KIT (WITH CALIBRATOR) 2. Brand Name :HbA1c DIRECT KIT (WITH CALIBRATOR) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of % HbA1c in human blood. 8. Material of Construction: HbA1c Direct R1: Latex, HbA1c Direct R2: Anti-human HbA1c mouse monoclonal antibody Anti-mouse IgG goat antibody, HbA1c R3: Haemolysis Reagent, HbA1c Direct Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
139	<ol style="list-style-type: none"> 1. Generic Name :HbA1c DIRECT MULTI Calibrator 2. Brand Name :HbA1c DIRECT MULTI Calibrator 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :HbA1c Direct calibrator is intended for the preparation of calibration curve for HbA1c Direct estimation 8. Material of Construction: HbA1c 4 Level Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
140	<ol style="list-style-type: none"> 1. Generic Name :HbA1c DIRECT MULTI Calibrator (4 Levels) 2. Brand Name :HbA1c DIRECT MULTI Calibrator (4 Levels) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :HbA1c Direct calibrator is intended for the preparation of calibration curve for HbA1c Direct estimation 8. Material of Construction: HbA1c 4 Level Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

141	<ol style="list-style-type: none"> 1. Generic Name :HbA1c hemolysing Reagent 2. Brand Name :HbA1c hemolysing Reagent 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of % HbA1c in human blood. 8. Material of Construction: HbA1c Direct R1: Latex, HbA1c Direct R2: Anti-human HbA1c mouse monoclonal antibody Anti-mouse IgG goat antibody, HbA1c R3: Haemolysis Reagent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
142	<ol style="list-style-type: none"> 1. Generic Name :HbA1c (With Calibrator) 2. Brand Name :HbA1c (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of % HbA1c in human blood. 8. Material of Construction: HbA1c Direct R1: Latex, HbA1c Direct R2: Anti-human HbA1c mouse monoclonal antibody Anti-mouse IgG goat antibody, HbA1c R3: Haemolysis Reagent, HbA1c Direct Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
143	<ol style="list-style-type: none"> 1. Generic Name :HDL Cholesterol Kit 2. Brand Name :HDL Cholesterol Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of HDL-Cholesterol in human serum. 8. Material of Construction: Reagent 1 R1: N—ethyl-N-(3-methylphenyl) -N' succinylethyenediame (EMSE) Reagent R2 Cholesterol Oxidase 4-Aminoantipyrin (4-AA) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
144	<ol style="list-style-type: none"> 1. Generic Name :HDL Cholesterol Direct 2. Brand Name :HDL Cholesterol Direct 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of HDLCholesterol in human serum 8. Material of Construction: Reagent 1 R1: N—ethyl-N-(3-methylphenyl) -N' succinylethyenediame (EMSE) Reagent R2 Cholesterol Oxidase 4-Aminoantipyrin (4-AA) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

145	<ol style="list-style-type: none"> 1. Generic Name :HDL-CHOLESTEROL CALIBRATOR SERUM 2. Brand Name :HDL-CHOLESTEROL CALIBRATOR SERUM 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This calibrator is intended for in vitro quantitative determination of HDL Cholesterol in serum or plasma. 8. Material of Construction: HDL–C Direct R1, HDL–C Direct R2, HDL–C Direct Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
146	<ol style="list-style-type: none"> 1. Generic Name :HDL-CHOLESTEROL DIRECT KIT (With Calibrator) 2. Brand Name :HDL-CHOLESTEROL DIRECT KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of HDL Cholesterol in serum or plasma. 8. Material of Construction: HDL–C Direct R1, HDL–C Direct R2, HDL–C Direct Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
147	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOGY ANALYZER E-Z CLEANER 2. Brand Name :HEMATOLOGY ANALYZER E-Z CLEANER 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :EZ cleaner is intended for daily cleaning of MINDRAY- 3 part Differential Hematology Analyzers of BC Series. 8. Material of Construction: Proteolytic enzyme, Substrate, Sodium chloride, Buffering agents, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
148	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOGY ANALYZER LYSE 2. Brand Name :HEMATOLOGY ANALYZER LYSE 3. Notified Category :Other than above substancesLysing Agent 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lyse is intended for lysing of cells for WBC Count and Hemoglobin measurement in MINDRAY-3 part Differential Hematology Analyzers of BC Series. 8. Material of Construction: Quaternary ammonium salts, Non-ionic surfactant, 2-Propanol 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

149	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOGY ANALYZER PROBE CLEANER 2. Brand Name :HEMATOLOGY ANALYZER PROBE CLEANER 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Probe cleaner is intended for periodical cleaning of sample probe in MINDRAY-3 part Differential Hematology Analyzers of BC Series. 8. Material of Construction: Surfactant, Sodium hypochlorite, Sodium chloride 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
150	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOGY ANALYZER RINSE 2. Brand Name :HEMATOLOGY ANALYZER RINSE 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Rinse is intended for cleaning the volumetric tubes of MINDRAY-3 part Differential Hematology Analyzers of BC Series. It is an azide free filtered solution. 8. Material of Construction: Sodium chloride, Sodium sulphate anhydrous, Buffering agents, Nonionic surfactant, Anti-fungal& Anti-bacterial agent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
151	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOGY CALIBRATOR ,WHOLE HUMAN BLOOD 2. Brand Name :HEMATOLOGY CALIBRATOR ,WHOLE HUMAN BLOOD 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :HEMATOLOGY CALIBRATOR, WHOLE HUMAN BLOOD is intended for the preparation of calibration curve for determination of hematology parameters. 8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
152	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3) WHOLE HUMAN BLOOD 2. Brand Name :HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3) WHOLE HUMAN BLOOD 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Hematology control used in monitoring of blood cell values on impedance cell counters. 8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

153	<p>1. Generic Name :HEMATOLOGY CONTROL (L) (HEMATOLOGY CONTROL LEVEL 1) WHOLE HUMAN BLOOD</p> <p>2. Brand Name :HEMATOLOGY CONTROL (L) (HEMATOLOGY CONTROL LEVEL 1)WHOLE HUMAN BLOOD</p> <p>3. Notified Category :Other than above substancesCalibrators/Controls</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Hematology control used in monitoring of blood cell values on impedance cell counters.</p> <p>8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
154	<p>1. Generic Name :HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3) WHOLE HUMAN BLOOD</p> <p>2. Brand Name :HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3) WHOLE HUMAN BLOOD</p> <p>3. Notified Category :Other than above substancesCalibrators/Controls</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Hematology control used in monitoring of blood cell values on impedance cell counters.</p> <p>8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
155	<p>1. Generic Name :Hematology Control (trilevel)(Combination Kit of hematology control (Low), hematology control (Normal), hematology control (High)).</p> <p>2. Brand Name :Hematology Control (trilevel)(Combination Kit of hematology control (Low), hematology control (Normal), hematology control (High)).</p> <p>3. Notified Category :Other than above substancesCalibrators/Controls</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Hematology control used in monitoring of blood cell values on impedance cell counters.</p> <p>8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>

156	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 1 2. Brand Name :HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 1 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Hematology control used in monitoring of blood cell values on impedance cell counters. 8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
157	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 2 2. Brand Name :HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 2 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Hematology control used in monitoring of blood cell values on impedance cell counters. 8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
158	<ol style="list-style-type: none"> 1. Generic Name :HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 3 2. Brand Name :HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 3 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Hematology control used in monitoring of blood cell values on impedance cell counters. 8. Material of Construction: human erythrocytes, mammalian leucocytes and mammalian platelets 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
159	<ol style="list-style-type: none"> 1. Generic Name :Hemoglobin Kit 2. Brand Name :Hemoglobin Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Hemoglobin in serum, plasma & urine. 8. Material of Construction: HEMOGLOBIN REAGENT - Potassium Phosphate,Potassium ferricyanide,Potassium cyanide, Sodium chloride. HEMOGLOBIN STANDARD - Cyanmethaemoglobin - Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

160	<p>1. Generic Name :HOMOCYSTEINE 2 REAGENT ENZYMATIc CALIBRATOR SET (5 LEVELS)</p> <p>2. Brand Name :HOMOCYSTEINE 2 REAGENT ENZYMATIc CALIBRATOR SET (5 LEVELS)</p> <p>3. Notified Category :Other than above substancesCalibrators/Controls</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for Homocysteine 2 Reagent Enzymatic estimation.</p> <p>8. Material of Construction: Homocysteine calibrator, Diluent</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
161	<p>1. Generic Name :HOMOCYSTEIN 2 REAGENT ENZYMATIc CONTROL SET (4 LEVELS) (LIQUID)</p> <p>2. Brand Name :HOMOCYSTEIN 2 REAGENT ENZYMATIc CONTROL SET (4 LEVELS) (LIQUID)</p> <p>3. Notified Category :Other than above substancesCalibrators/Controls</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :The Liquid Stable (LS) 2-part Homocysteine Reagent is intended for invitro quantitative determination of total homocysteine in human serum and plasma.</p> <p>8. Material of Construction: Reagent 1 (R1): NADH, LDH, Serine, Trizma Base, Trizma Hydrochloride, Sodium Azide, Reductant. Reagent 2 (R2): Cycling Enzymes</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
162	<p>1. Generic Name :HOMOCYSTEINE 2 REAGENT ENZYMATIc KIT</p> <p>2. Brand Name :HOMOCYSTEINE 2 REAGENT ENZYMATIc KIT</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diagnostic Medical Device for the detection of Homocysteine in serum.</p> <p>8. Material of Construction: Homocysteine R1, Homocysteine R2</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
163	<p>1. Generic Name :IgA Mispa i3</p> <p>2. Brand Name :IgA Mispa i3</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :12 months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of I (IgA I3) in human serum</p> <p>8. Material of Construction: Reagent 1 R1: Tris(hydroxymethyl) amino methane with PEG Reagent 2 R2: Anti-human IgA I3 antiserum.</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>

164	<ol style="list-style-type: none"> 1. Generic Name :IgE Calibrator 2. Brand Name :IgE Calibrator 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :IgE Calibrator is intended for the preparation of calibration curve for IgE estimation. 8. Material of Construction: Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
165	<ol style="list-style-type: none"> 1. Generic Name :IgE CARTRIDGE (Mispa- i3) 2. Brand Name :IgE CARTRIDGE (Mispa- i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Immunoglobulin A (IgE CARTRIDGE (Mispa- i3)) in human serum 8. Material of Construction: Reagent 1 R1: Tris(hydroxymethyl) amino methane with PEG Reagent 2 R2: Anti-human IgE CARTRIDGE (Mispa- i3) antiserum. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
166	<ol style="list-style-type: none"> 1. Generic Name :IgG(Mispa-i3) 2. Brand Name :IgG(Mispa-i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of IgG (Mispa-i3) in human serum 8. Material of Construction: Reagent 1 R1: Tris Buffer Reagent 2 R2 : Anti-human IgG antiserum Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
167	<ol style="list-style-type: none"> 1. Generic Name :IgM (Mispa-i3) 2. Brand Name :IgM (Mispa-i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Immunoglobulin M (IgM (Mispa-i3)) in human serum 8. Material of Construction: Reagent 1 R1: Tris(hydroxymethyl) amino methane with PEG Reagent 2 R2: PolyclonalAnti-human C4 antibody 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

168	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOGLOBULIN A(IgA) KIT 2. Brand Name :IMMUNOGLOBULIN A(IgA) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Immunoglobulin A (IMMUNOGLOBULIN A(IgA) KIT) in human serum 8. Material of Construction: Reagent 1 R1: Tris(hydroxymethyl) amino methane with PEG Reagent 2 R2: Anti-human IMMUNOGLOBULIN A(IgA) KIT antiserum. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
169	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOGLOBULIN A (IgA) KIT (With Calibrator) 2. Brand Name :IMMUNOGLOBULIN A (IgA) KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of IgA antibodies, in serum 8. Material of Construction: IgA R1 (Buffer Solution), IgA R2 (Antiserum solution), Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
170	<ol style="list-style-type: none"> 1. Generic Name :IgE CARTRIDGE (Mispa- i3) 2. Brand Name :IgE CARTRIDGE (Mispa- i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Immunoglobulin (IgE CARTRIDGE (Mispa- i3) in human serum 8. Material of Construction: Reagent 1 R1: Glycine buffer Reagent 2 R2: IgE CARTRIDGE (Mispa- i3) Latex suspension particles coated anti IgE CARTRIDGE (Mispa- i3) antibodies. 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
171	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOGLOBULIN E (IgE) KIT (With Calibrator) 2. Brand Name :IMMUNOGLOBULIN E (IgE) KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of IgE in human serum. 8. Material of Construction: Glycine buffer solution, Latex suspension, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

172	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOGLOBULIN G (IgG) KIT (With Calibrator) 2. Brand Name :IMMUNOGLOBULIN G (IgG) KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of IgG antibodies in serum 8. Material of Construction: IgG R1: Tris(hydroxymethyl) aminomethane, IgG R2: Anti-human IgG antiserum, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
173	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOGLOBULIN G(IgG)KIT 2. Brand Name :IMMUNOGLOBULIN G(IgG)KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of immunoglobulin G in human serum 8. Material of Construction: Reagent 1 R1: Tris Buffer Reagent 2 R2 : Anti-human IgG antiserum Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
174	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOGLOBULIN M(IgM)KIT 2. Brand Name :IMMUNOGLOBULIN M(IgM)KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Immunoglobulin M (IgM) in human serum 8. Material of Construction: Reagent 1 R1: Tris(hydroxymethyl) amino methane with PEG Reagent 2 R2: PolyclonalAnti-human C4 antibody 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
175	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOGLOBULIN M (IgM) KIT (With Calibrator) 2. Brand Name :IMMUNOGLOBULIN M (IgM) KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of IgM antibodies in serum 8. Material of Construction: IgM R1: Tris(hydroxymethyl) aminomethane, IgM R2: Anti-human IgM antiserum, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

176	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOLOGY CALIBRATOR HUMAN SERUM 2. Brand Name :IMMUNOLOGY CALIBRATOR HUMAN SERUM 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for the preparation of reference curves for quantitative immunochemical determination of protein in human serum. 8. Material of Construction: Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
177	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOLOGY CONTROL LEVEL 1 2. Brand Name :IMMUNOLOGY CONTROL LEVEL 1 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :IMMUNOLOGY CONTROL LEVEL 1 is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: IMMUNOLOGY CONTROL LEVEL 1 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
178	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOLOGY CONTROL LEVEL 2 2. Brand Name :IMMUNOLOGY CONTROL LEVEL 2 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :IMMUNOLOGY CONTROL LEVEL 2 is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: IMMUNOLOGY CONTROL LEVEL 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
179	<ol style="list-style-type: none"> 1. Generic Name :IMMUNOLOGY CONTROL LEVEL 3 2. Brand Name :IMMUNOLOGY CONTROL LEVEL 3 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :IMMUNOLOGY CONTROL LEVEL 3 is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: IMMUNOLOGY CONTROL LEVEL 3 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

180	<ol style="list-style-type: none"> 1. Generic Name :INORGANIC PHOSPHOROUS KIT 2. Brand Name :INORGANIC PHOSPHOROUS KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of INORGANIC PHOSPHOROUS , in serum, plasma & urine. 8. Material of Construction: Sulfuric Acid, Ammonium molybdate, Phosphorous Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
181	<ol style="list-style-type: none"> 1. Generic Name :IRON Reagent Kit 2. Brand Name :IRON Reagent Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Iron in serum. 8. Material of Construction: Acetate Buffer, CTMA Bromide, Cromazurol B 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
182	<ol style="list-style-type: none"> 1. Generic Name :IRON/TIBC CALIBRATOR 2. Brand Name :IRON/TIBC CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :IRON/TIBC CALIBRATOR is intended for the preparation of calibration curve for IRON /TIBC estimation. 8. Material of Construction: Tris-HCl, Adenosine, EHSPT 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
183	<ol style="list-style-type: none"> 1. Generic Name :KAPPA LIGHT CHAIN 2. Brand Name :KAPPA LIGHT CHAIN 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of kappa light chain in human serum. 8. Material of Construction: Reagent 1 R1: MES Buffer Reagent 2 R2 : Polyclonal goat anti-human kappa light chain Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

184	<ol style="list-style-type: none"> 1. Generic Name :Kappa Light Chain(Mispa-i3) (KLC) 2. Brand Name :Kappa Light Chain(Mispa-i3) (KLC) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Kappa Light Chain(Mispa-i3) in human serum. 8. Material of Construction: Reagent 1 R1: MES Buffer Reagent 2 R2 : Polyclonal goat anti-human Kappa Light Chain(Mispa-i3) Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
185	<ol style="list-style-type: none"> 1. Generic Name :Kit Protein control bi-level 2. Brand Name :Kit Protein control bi-level 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Kit Protein control bi-level (immunology control) is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: Kit Protein control bi-level 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
186	<ol style="list-style-type: none"> 1. Generic Name :LAMBDA LIGHT CHAIN 2. Brand Name :LAMBDA LIGHT CHAIN 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of lambda light chain in human serum 8. Material of Construction: Reagent 1 R1: MES Buffer Reagent 2 R2 Polyclonal goat anti-human lambda light chain Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
187	<ol style="list-style-type: none"> 1. Generic Name :Lambda Light Chain (Mispa -i3) 2. Brand Name :Lambda Light Chain (Mispa -i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of lambda light chain in human serum 8. Material of Construction: Reagent 1 R1: MES Buffer Reagent 2 R2 Polyclonal goat anti-human lambda light chain Reagent R3: Normal Saline 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

188	<ol style="list-style-type: none"> 1. Generic Name :LDH-P (SL) KIT 2. Brand Name :LDH-P (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of LDH-P in human serum 8. Material of Construction: Reagent 1 R1: Tris buffer, pyruvate, sodium chloride Reagent 2 R2: NADH 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
189	<ol style="list-style-type: none"> 1. Generic Name :LDH-P KIT 2. Brand Name :LDH-P KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of LDH-P in human serum 8. Material of Construction: Reagent 1 R1: Tris buffer, pyruvate, sodium chloride Reagent 2 R2: NADH 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
190	<ol style="list-style-type: none"> 1. Generic Name :LDL-CHOLESTEROL CALIBRATOR SERUM 2. Brand Name :LDL-CHOLESTEROL CALIBRATOR SERUM 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This calibrator is intended for in vitro quantitative determination of LDL Cholesterol in serum or plasma. 8. Material of Construction: LDL –C Direct R1- HSDA, Good's buffer. LDL –C Direct R2 - Cholesterol esterase,Cholesterol oxidase, 4-Aminoantipyrin, Good's buffer. LDL –C Direct Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
191	<ol style="list-style-type: none"> 1. Generic Name :LDL Cholesterol Direct 2. Brand Name :LDL Cholesterol Direct 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of LDL-Cholesterol in human serum 8. Material of Construction: Reagent 1 R1: HSDA, Goods buffer Reagent R2: Cholesterol esterase , Cholesterol oxidase ,4-Aminoantipyrin ,Good's buffer 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

192	<ol style="list-style-type: none"> 1. Generic Name :LDL-CHOLESTEROL DIRECT KIT (With Calibrator) 2. Brand Name :LDL-CHOLESTEROL DIRECT KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of LDL Cholesterol in serum or plasma. 8. Material of Construction: LDL –C Direct R1: HSDA, Good's buffer. LDL –C Direct R2: Cholesterol esterase, Cholesterol oxidase, 4-Aminoantipyrin, Good's buffer. LDL –C Direct Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
193	<ol style="list-style-type: none"> 1. Generic Name :LIPASE (SL) KIT 2. Brand Name :LIPASE (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Lipase in human serum 8. Material of Construction: Goods Buffer, Taurodeoxycholate, Deoxycholate, Calcium chloride, Colipase, Tartarate Buffer, color substrate 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
194	<ol style="list-style-type: none"> 1. Generic Name :LIPASE KIT 2. Brand Name :LIPASE KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Lipase in human serum 8. Material of Construction: Goods Buffer, Taurodeoxycholate, Deoxycholate, Calcium chloride, Colipase, Tartarate Buffer, color substrate 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
195	<ol style="list-style-type: none"> 1. Generic Name :LIPID CALIBRATOR SERUM 2. Brand Name :LIPID CALIBRATOR SERUM 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lipid Calibrator is intended for the preparation of calibration curve for Lipid estimation. 8. Material of Construction: Lipid Control Level 1 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

196	<ol style="list-style-type: none"> 1. Generic Name :LIPID CONTROL HUMAN SERUM LEVEL 1 2. Brand Name :LIPID CONTROL HUMAN SERUM LEVEL 1 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lipid Control is an assayed lyophilized quality control serum intended to monitor the accuracy and precision of ApoA1, Apo B, Lp (a), HDL-D, LDL-D, TGL & Cholesterol. 8. Material of Construction: Lipid Control Level 1, Lipid Control Level 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
197	<ol style="list-style-type: none"> 1. Generic Name :LIPID CONTROL, HUMAN SERUM LEVEL 2 2. Brand Name :LIPID CONTROL, HUMAN SERUM LEVEL 2 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lipid Control is an assayed lyophilized quality control serum intended to monitor the accuracy and precision of ApoA1, Apo B, Lp (a), HDL-D, LDL-D, TGL & Cholesterol. 8. Material of Construction: Lipid Control Level 1, Lipid Control Level 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
198	<ol style="list-style-type: none"> 1. Generic Name :Lp(a) (Mispa-i3) 2. Brand Name :Lp(a) (Mispa-i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Lipoprotein(a) [Lp(a)] in human serum 8. Material of Construction: Reagent 1 R1:buffer solution Reagent 2 R2: Latex suspension particles coated anti Lp(a) antibodies. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
199	<ol style="list-style-type: none"> 1. Generic Name :LP (a) CALIBRATOR 2. Brand Name :LP (a) CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lp (a) Calibrator is intended for the preparation of calibration curve for Lp (a) estimation. 8. Material of Construction: Lipoprotein (a) calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

200	<ol style="list-style-type: none"> 1. Generic Name :Lp(a) LIPOPROTEIN (a) KIT 2. Brand Name :Lp(a) LIPOPROTEIN (a) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Lipoprotein(a) [Lp(a)] in human serum 8. Material of Construction: Reagent 1 R1:buffer solution Reagent 2 R2: Latex suspension particles coated anti Lp(a) antibodies. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
201	<ol style="list-style-type: none"> 1. Generic Name :Lp (a) LIPOPROTEIN (a) KIT (WITH CALIBRATOR) 2. Brand Name :Lp (a) LIPOPROTEIN (a) KIT (WITH CALIBRATOR) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Lipoprotein (a) in serum. 8. Material of Construction: Lipoprotein (a) R1: Buffer solution, Lipoprotein (a) R2: Lipoprotein (a) latex, Lipoprotein (a) calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
202	<ol style="list-style-type: none"> 1. Generic Name :Lp (a) Latex 2. Brand Name :Lp (a) Latex 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :1.5 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Quantitative determination of Lipoprotein (a) (Lp(a)) IVD 8. Material of Construction: R1: Glycine buffer, Sodium azide R2: Latex particles coated with mouse monoclonal antihuman Lp (a), Sodium azide, Saline Solution 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
203	<ol style="list-style-type: none"> 1. Generic Name :Lp (a) Latex control 2. Brand Name :Lp (a) Latex control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lp (a) Latex Control is an assayed quality control intended for monitoring the precision of laboratory testing procedures. 8. Material of Construction: Lp (a) Latex Control 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

204	<ol style="list-style-type: none"> 1. Generic Name :Lyse for BC 2800 (Lyse (BC-2800)) 2. Brand Name :Lyse for BC 2800 (Lyse (BC-2800)) 3. Notified Category :Other than above substancesLysing Agent 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Lyse is intended for lysing of cells for WBC Count and Hemoglobin measurement in MINDRAY-3 part Differential Hematology Analyzers of BC Series. 8. Material of Construction: Quaternary ammonium salts, Non-ionic surfactant, 2-Propanol 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
205	<ol style="list-style-type: none"> 1. Generic Name :Lyse Solution for 5-Part Hematology Analyzer (diff. L5 analyzer) 2. Brand Name :Lyse Solution for 5-Part Hematology Analyzer (diff. L5 analyzer) 3. Notified Category :Other than above substancesLysing Agent 4. Class of Medical Device :Class A 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diff L5 is intended for lysing of cells for WBC Count, WBC differentials and Hemoglobin measurement in Mispa Count plus -5 part Differential Hematology Analyzer. 8. Material of Construction: Dodecyl Trimethyl Ammonium Chloride, Dodecyl Trimethyl Ammonium Bromide, Hexamine, IPA, 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
206	<ol style="list-style-type: none"> 1. Generic Name :Lyse Solution for 5-Part Hematology Analyzer(LYSE DS500) 2. Brand Name :Lyse Solution for 5-Part Hematology Analyzer(LYSE DS500) 3. Notified Category :Other than above substancesLysing Agent 4. Class of Medical Device :Class A 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diff L5 is intended for lysing of cells for WBC Count, WBC differentials and Hemoglobin measurement in Mispa Count plus -5 part Differential Hematology Analyzer. 8. Material of Construction: Dodecyl Trimethyl Ammonium Chloride, Dodecyl Trimethyl Ammonium Bromide, Hexamine, IPA, 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
207	<ol style="list-style-type: none"> 1. Generic Name :MAGNESIUM KIT 2. Brand Name :MAGNESIUM KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Magnesium in serum ,plasma and urine. 8. Material of Construction: MAGNESIUM REAGENT: Xylidyl Blue, 110 mmol/L Ethanolamine, GEDTA. MAGNESIUM STANDARD 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

208	<ol style="list-style-type: none"> 1. Generic Name :MICROALBUMIN CALIBRATOR 2. Brand Name :MICROALBUMIN CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Microalbumin calibrator is intended for the preparation of calibration curve for Microalbumin estimation. 8. Material of Construction: Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
209	<ol style="list-style-type: none"> 1. Generic Name :MICROALBUMIN CARTRIDGE (Mispa -i3) 2. Brand Name :MICROALBUMIN CARTRIDGE (Mispa -i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of microprotein in human serum 8. Material of Construction: Reagent 1 R1: Glycine buffer Solution Reagent 2 R2: Latex suspension anti human Albumin stabilizers 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
210	<ol style="list-style-type: none"> 1. Generic Name :Microalbumin Control 2. Brand Name :Microalbumin Control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Microalbumin Control is an assayed quality control intended for monitoring the accuracy and precision of Microalbumin assay. 8. Material of Construction: Microalbumin Control Level 1, Microalbumin Control Level 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
211	<ol style="list-style-type: none"> 1. Generic Name :Microalbumin Test Kit 2. Brand Name :MICROALBUMIN IT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of microalbumin in human urine 8. Material of Construction: Microalbumin R1: Saline, Accelerator, Sodium azide. Microalbumin R2: Phosphate buffered saline, Polyclonal goat anti-human albumin, Sodium azide. Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

212	<ol style="list-style-type: none"> 1. Generic Name :MICROALBUMIN IT (With Calibrator) 2. Brand Name :MICROALBUMIN IT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of microalbumin in human urine 8. Material of Construction: Microalbumin R1: Saline, Accelerator, Sodium azide. Microalbumin R2: Phosphate buffered saline, Polyclonal goat anti-human albumin, Sodium azide. Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
213	<ol style="list-style-type: none"> 1. Generic Name :Microalbumin Latex 2. Brand Name :Microalbumin Latex 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Quantitative determination of Microalbumin (ALB) – IVD 8. Material of Construction: R1:Glycine buffer, Sodium azide. R2: Particles coated goat IgG with anti-human albumin, Sodium azide. Saline Solution, Microalbumin Latex Control. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
214	<ol style="list-style-type: none"> 1. Generic Name :MICROALBUMIN LATEX CONTROL 2. Brand Name :MICROALBUMIN LATEX CONTROL 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Microalbumin Latex control is an assayed quality control intended for monitoring the accuracy and precision of Microalbumin assay. 8. Material of Construction: Microalbumin Latex control Level 1, Microalbumin Latex control Level 2 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
215	<ol style="list-style-type: none"> 1. Generic Name :MICROALBUMIN TURBILATEX KIT (WITH CALIBRATOR) 2. Brand Name :MICROALBUMIN TURBILATEX KIT (WITH CALIBRATOR) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Alpha1-Acid Glycoprotein in human serum. 8. Material of Construction: Microalbumin R1: Diluent, Glycine buffer, Sodium azide. Microalbumin R2: Latex, Suspension of latex particles coated with anti-human Albumin, Sodium azide. Microalbumin calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

216	<ol style="list-style-type: none"> 1. Generic Name :MICROPROTEIN CALIBRATOR 2. Brand Name :MICROPROTEIN CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :MICROPROTEIN CALIBRATOR is intended for the preparation of calibration curve for IRON estimation. 8. Material of Construction: Tris-HCl, Adenosine, EHSPT 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
217	<ol style="list-style-type: none"> 1. Generic Name :MICRPROTIEN KIT 2. Brand Name :MICRPROTIEN KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of microprotein in human serum 8. Material of Construction: Reagent 1 R1: Glycine buffer Solution Reagent 2 R2: Latex suspension anti human Albumin stabilizers 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
218	<ol style="list-style-type: none"> 1. Generic Name :Mispa i3 probe Cleaner 2. Brand Name :Mispa i3 probe Cleaner 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Mispa i3 Probe Cleaner is intended for periodic and routine cleaning of aspiration probe and washing station of Mispa i3 Specific Protein Analyzer. Mispa i3 Probe Cleaner is a strong alkaline cleaning agent used to remove residual specimen and the remaining reagents contained in the aspiration probe and washing probe of analyzer. It removes any residual cellular, proteinaceous deposits (serum albumin) and the remaining reagents that may appear during the operation of the analyzer. 8. Material of Construction: Sodium Hypochlorite 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
219	<ol style="list-style-type: none"> 1. Generic Name :Mispa i3 washing solution 2. Brand Name :Mispa i3 washing solution 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Mispa i3 Wash Solution is intended for cleansing and maintenance of aspiration probes of Mispa i3 Specific Protein Analyzer 8. Material of Construction: Detergent, Stabilizers, Preservatives 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

220	<ol style="list-style-type: none"> 1. Generic Name :Mispa Mini Detergent Solution 2. Brand Name :Mispa Mini Detergent Solution 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for cleansing and maintenance of reaction cuvette and aspiration probes of Mispa Mini - Random Access Clinical Chemistry Analyzer. 8. Material of Construction: Alkaline solution, Stabilizer, Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
221	<ol style="list-style-type: none"> 1. Generic Name :Mispa Nano washing solution (Washing solution(AI)) 2. Brand Name :Mispa Nano washing solution (Washing solution(AI)) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class A 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for cleansing and maintenance of reaction cuvette and aspiration probes of Mispa Nano - Random Access Clinical Chemistry Analyzer. 8. Material of Construction: Alkaline solution, Stabilizer, Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
222	<ol style="list-style-type: none"> 1. Generic Name :MULTICALIBRATOR (Clinical Chemistry Multicalibrator) 2. Brand Name :MULTICALIBRATOR (Clinical Chemistry Multicalibrator) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Multicalibrator is a calibration serum intended for calibration of clinical chemistry assays suitable for manual procedure and automated analyzers. 8. Material of Construction: Multicalibrator, Lyophilized human serum with additives, Bacteriostatic agents and stabilizers. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
223	<ol style="list-style-type: none"> 1. Generic Name :MYOGLOBIN REAGENT KIT 2. Brand Name :MYOGLOBIN REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of myoglobin in serum. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is Latex particles coated with mouse monoclonal anti-human IgE. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

224	<ol style="list-style-type: none"> 1. Generic Name :MYOGLOBIN (MISPA I3) REAGENT KIT 2. Brand Name :MYOGLOBIN (MISPA I3) REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Myoglobin (MISPA i3) in serum. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is Latex particles coated with mouse monoclonal anti-human IgE. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
225	<ol style="list-style-type: none"> 1. Generic Name :MYOGLOBIN CALIBRATOR SET (6 LEVELS) (LIQUID) 2. Brand Name :MYOGLOBIN CALIBRATOR SET (6 LEVELS) (LIQUID) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for Myoglobin estimation. 8. Material of Construction: Myoglobin calibrator, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
226	<ol style="list-style-type: none"> 1. Generic Name :MYOGLOBIN CONTROL SET (2 LEVELS) (LIQUID) 2. Brand Name :MYOGLOBIN CONTROL SET (2 LEVELS) (LIQUID) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Myoglobin Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of Myoglobin in human serum. 8. Material of Construction: Myoglobin Control, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
227	<ol style="list-style-type: none"> 1. Generic Name :MYOGLOBIN LIQUID STABLE [SL] REAGENT KIT 2. Brand Name :MYOGLOBIN LIQUID STABLE [SL] REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Myoglobin in serum. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is Latex particles coated with mouse monoclonal anti-human IgE. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

228	<ol style="list-style-type: none"> 1. Generic Name :N- ACETYL--D-GLUCOSAMINIDASE (NAG) CALIBRATOR SET 2. Brand Name :N- ACETYL--D-GLUCOSAMINIDASE (NAG) CALIBRATOR SET 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for N- Acetyl--D-Glucosaminidase (NAG) estimation. 8. Material of Construction: NAG calibrator, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
229	<ol style="list-style-type: none"> 1. Generic Name :N-ACETYL-b-D- GLUCOSAMINIDASE (NAG) CONTROL SET 2 LEVELS 2. Brand Name :N-ACETYL-b-D- GLUCOSAMINIDASE (NAG) CONTROL SET 2 LEVELS 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :N-Acetyl-b-D- Glucosaminidase (NAG) Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of N-Acetyl-b-D- Glucosaminidase (NAG) in human serum. 8. Material of Construction: NAG control, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
230	<ol style="list-style-type: none"> 1. Generic Name :N- ACETYL--D-GLUCOSAMINIDASE (NAG) REAGENT KIT 2. Brand Name :N- ACETYL--D-GLUCOSAMINIDASE (NAG) REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of N- Acetyl--D- Glucosaminidase antibody in serum. 8. Material of Construction: Buffer solution, Synthesised polystyrene latex particles coated with H.pylori antigens 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
231	<ol style="list-style-type: none"> 1. Generic Name :POTASSIUM KIT 2. Brand Name :POTASSIUM KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of potassium in serum or plasma. 8. Material of Construction: Sodium tetraphenyl boron, Potassium Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

232	<ol style="list-style-type: none"> 1. Generic Name :PREALBUMIN KIT 2. Brand Name :PREALBUMIN KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of prealbumin in human serum 8. Material of Construction: Reagent 1 R1: Tris(hydroxymethyl) aminomethane buffer Reagent 2 R2: Polyclonal goat anti-human prealbumin antibodies stabilized 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
233	<ol style="list-style-type: none"> 1. Generic Name :PREALBUMIN (MISPA i3) REAGENT KIT 2. Brand Name :PREALBUMIN (MISPA i3) REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Prealbumin in serum 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is latex particle coated with antibody 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
234	<ol style="list-style-type: none"> 1. Generic Name :PREALBUMIN (With Calibrator) 2. Brand Name :PREALBUMIN (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Prealbumin in human serum 8. Material of Construction: Prealbumin R1 - Tris (hydroxymethyl) aminomethane, Prealbumin R2 - Anti- human prealbumin anti-serum, Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
235	<ol style="list-style-type: none"> 1. Generic Name :Probe cleaner for 3 - part differential hematology analyzer Count P3 2. Brand Name :Probe cleaner for 3 - part differential hematology analyzer Count P3 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Count P3 is intended for periodical cleaning of sample probe, counting chamber,optical bench and tubing in Mispa count 5 part Differential Hematology Analyzer. 8. Material of Construction: Surfactant, Sodium hypochlorite, Sodium chloride 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

236	<ol style="list-style-type: none"> 1. Generic Name :Probe cleaner for 5 - part differential hematology analyzer (diff. P5) 2. Brand Name :Probe cleaner for 5 - part differential hematology analyzer (diff. P5) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diff P5 is intended for periodical cleaning of sample probe, counting chamber,optical bench and tubing in Mispa Count plus 5 part Differential Hematology Analyzer. 8. Material of Construction: Surfactant, Sodium hypochlorite, Sodium chloride 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
237	<ol style="list-style-type: none"> 1. Generic Name :PROCALCITONIN REAGENT KIT 2. Brand Name :PROCALCITONIN REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of PCT in human serum. For in vitro diagnostic use only. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is latex particle coated with antibody 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
238	<ol style="list-style-type: none"> 1. Generic Name :PROCALCITONIN CALIBRATOR SET (2 LEVELS) LYOPHILIZED 2. Brand Name :PROCALCITONIN CALIBRATOR SET (2 LEVELS) LYOPHILIZED 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for Procalcitonin estimation. 8. Material of Construction: PCT lyophized calibrator, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
239	<ol style="list-style-type: none"> 1. Generic Name :PROCALCITONIN CONTROL SET 2. Brand Name :PROCALCITONIN CONTROL SET 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Procalcitonin Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of Procalcitonin in human serum. 8. Material of Construction: PCT control, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

240	<ol style="list-style-type: none"> 1. Generic Name :PROCALCITONIN (MISPA i3) REAGENT KIT 2. Brand Name :PROCALCITONIN (MISPA i3) REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of PCT in human serum. For in vitro diagnostic use only. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is latex particle coated with antibody. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
241	<ol style="list-style-type: none"> 1. Generic Name :PROTEIN CALIBRATOR (IMMUNOLOGY CALIBRATOR) 2. Brand Name :PROTEIN CALIBRATOR (IMMUNOLOGY CALIBRATOR) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for the preparation of reference curves for quantitative immunochemical determination of protein in human serum. 8. Material of Construction: Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
242	<ol style="list-style-type: none"> 1. Generic Name :Protein Control 2. Brand Name :Protein Control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Protein control (immunology control) is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: Protein Control 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
243	<ol style="list-style-type: none"> 1. Generic Name :PROTEIN CONTROL (IMMUNOLOGY CONTROL) 2. Brand Name :PROTEIN CONTROL (IMMUNOLOGY CONTROL) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :PROTEIN CONTROL (IMMUNOLOGY CONTROL) is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: PROTEIN CONTROL (IMMUNOLOGY CONTROL) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

244	<ol style="list-style-type: none"> 1. Generic Name :PROTEIN CONTROL (Immunology control, level 1) 2. Brand Name :PROTEIN CONTROL (Immunology control, level 1) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :PROTEIN CONTROL (IMMUNOLOGY CONTROL, LEVEL 1) is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: PROTEIN CONTROL (IMMUNOLOGY CONTROL, LEVEL 1) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
245	<ol style="list-style-type: none"> 1. Generic Name :Protein Control (Lypho) 2. Brand Name :Protein Control (Lypho) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Immunology control is an assayed quality control intended for monitoring the precision of laboratory testing procedures. 8. Material of Construction: Protein Control (Lypho) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
246	<ol style="list-style-type: none"> 1. Generic Name :Qualicheck Norm & Path (Combination kit of Qualicheck Path) 2. Brand Name :Qualicheck Norm & Path (Combination kit of Qualicheck Path) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Immunology control is an assayed quality control intended for monitoring the precision of laboratory testing procedures. 8. Material of Construction: Qualicheck Norm & Path (Combination kit of Qualicheck Path) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
247	<ol style="list-style-type: none"> 1. Generic Name :QUALICHECK NORM (Clinical Chemistry Control level 2) 2. Brand Name :QUALICHECK NORM (Clinical Chemistry Control level 2) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Qualicheck Norm is an assayed human serum used for quality control checking of clinical chemistry assays suitable for manual procedure and automated analyzers. 8. Material of Construction: QUALICHECK NORM (Clinical Chemistry Control level 2) Level 1 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

248	<ol style="list-style-type: none"> 1. Generic Name :QUALICHECK PATH (Clinical Chemistry Control, level 1) 2. Brand Name :QUALICHECK PATH (Clinical Chemistry Control, level 1) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Qualicheck Path is an assayed human serum used for quality control checking of clinical chemistry assays suitable for manual procedure and automated analyzers. 8. Material of Construction: QUALICHECK PATH (Clinical Chemistry Control level 1) Level 1 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
249	<ol style="list-style-type: none"> 1. Generic Name :RETINOL BINDING PROTEIN (RBP) CALIBRATOR SET (5 LEVELS) (LIQUID) 2. Brand Name :RETINOL BINDING PROTEIN (RBP) CALIBRATOR SET (5 LEVELS) (LIQUID) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for Retinol binding protein (RBP) estimation. 8. Material of Construction: RBP Calibrator, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
250	<ol style="list-style-type: none"> 1. Generic Name :RETINOL BINDING PROTEIN (RBP) CONTROL SET 2 LEVELS 2. Brand Name :RETINOL BINDING PROTEIN (RBP) CONTROL SET 2 LEVELS 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Retinol binding protein (RBP) Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of Retinol binding protein (RBP) in human serum. 8. Material of Construction: RBP control, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
251	<ol style="list-style-type: none"> 1. Generic Name :RETINOL BINDING PROTEIN (RBP) REAGENT KIT 2. Brand Name :RETINOL BINDING PROTEIN (RBP) REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the measurement of retinol binding protein (RBP) in serum. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is latex particle with antibody-sensitized Anti- RBP rabbit. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

252	<ol style="list-style-type: none"> 1. Generic Name :RF CALIBRATOR (Immunology calibrator) 2. Brand Name :RF CALIBRATOR (Immunology calibrator) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for the preparation of calibration curve for RF estimation. 8. Material of Construction: RF CALIBRATOR 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
253	<ol style="list-style-type: none"> 1. Generic Name :RF Cartridge (Mispa - i3) 2. Brand Name :RF Cartridge (Mispa - i3) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :12 months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of RF in human serum 8. Material of Construction: Reagent 1 R1: Glycine buffer Reagent 2 R2: Latex suspension coated with denatured human IgG 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
254	<ol style="list-style-type: none"> 1. Generic Name :RF Test Kit 2. Brand Name :RF Latex 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for the in vitro quantitative determination of Rheumatoid Factor (RF) in human serum using the Turbi-Quick system. 8. Material of Construction: R1 - Glycine, Detergent. R2 - Glycine buffer, Human IgG sensitised latex 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
255	<ol style="list-style-type: none"> 1. Generic Name :RF Latex control 2. Brand Name :RF Latex control 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Quantitative determination of Rheumatoid Factor (RF) IVD 8. Material of Construction: RF Latex Control 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

256	<ol style="list-style-type: none"> 1. Generic Name :RF LATEX SLIDE KIT 2. Brand Name :RF LATEX SLIDE KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro qualitative & semi quantitative determination of Rheumatoid factor (RF) in serum. 8. Material of Construction: RF LATEX, RF Positive Control, RF Negative Control, Physiological Saline, Buffer Concentrate, 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
257	<ol style="list-style-type: none"> 1. Generic Name :RF LATEX SLIDE KIT (RF) 2. Brand Name :RF LATEX SLIDE KIT (RF) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro qualitative & semi quantitative determination of Rheumatoid factor (RF) in serum. 8. Material of Construction: RF LATEX, RF Positive Control, RF Negative Control, Physiological Saline, Buffer Concentrate, 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
258	<ol style="list-style-type: none"> 1. Generic Name :RF TURBILATEX KIT (WITH CALIBRATOR) 2. Brand Name :RF TURBILATEX KIT (WITH CALIBRATOR) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Rheumatoid factor in serum. 8. Material of Construction: RF TURBILATEX R1 - Diluent, Tris buffer, Sodium azide. RF TURBILATEX R2 - Suspension of latex particles coated with human gamma-globulin.. RF CALIBRATOR 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
259	<ol style="list-style-type: none"> 1. Generic Name :RF with calibrator 2. Brand Name :RF with calibrator 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro qualitative & semi quantitative determination of Rheumatoid factor (RF) in serum. 8. Material of Construction: Glycine buffer solution with calibrator suspension coated with denatured human IgG, RF calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

260	<ol style="list-style-type: none"> 1. Generic Name :Serum Protein control (Bi-level Protein control) 2. Brand Name :Serum Protein control (Bi-level Protein control) 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :SERUM PROTEIN CONTROL (BILEVEL PROTEIN CONTROL) is an assayed quality control intended for monitoring the precision of laboratory testing procedures of specific proteins. 8. Material of Construction: SERUM PROTEIN CONTROL (BILEVEL PROTEIN CONTROL) 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
261	<ol style="list-style-type: none"> 1. Generic Name :SGOT Test Kit 2. Brand Name :SGOT Test Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of SGOT in serum or plasma. 8. Material of Construction: SGOT R1 - Tris Buffer, L-Aspartate. SGOT R2 - MDH, LDH, NADH, a -ketoglutarate 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
262	<ol style="list-style-type: none"> 1. Generic Name :SGPT (SL) KIT 2. Brand Name :SGPT (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of SGOT in human serum 8. Material of Construction: SGOT Reagent, Tris buffer, L-aspartate, LDH 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
263	<ol style="list-style-type: none"> 1. Generic Name :SGPT (SL) KIT 2. Brand Name :SGPT (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of SGPT in human serum 8. Material of Construction: SGPT Reagent, Tris buffer, L-Alanine, LDH, lpha-ketoglutarate, NADH 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

264	<ol style="list-style-type: none"> 1. Generic Name :SGPT Test Kit 2. Brand Name :SGPT Test Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of SGPT in serum or plasma. 8. Material of Construction: SGPT R1 - Tris Buffer, L-Alanine. SGPT R2 - LDH, NADH, a - ketoglutarate 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
265	<ol style="list-style-type: none"> 1. Generic Name :Sheath solution (Cleaning and flow control medium solution for 5-part hematology analyzer) 2. Brand Name :Sheath solution (Cleaning and flow control medium solution for 5-part hematology analyzer) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Sheath Solution is intended for cleaning the tubing's of Mispa Count-5 part Differential Hematology Analyzer. It is an azide free filtered solution. 8. Material of Construction: Boric acid, Sodium chloride, Sodium sulphate, EDTA, CWT 3030, TRITON, Proteolytic enzyme 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
266	<ol style="list-style-type: none"> 1. Generic Name :SODIUM KIT 2. Brand Name :SODIUM KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Sodium in serum. 8. Material of Construction: Sodium R1 - Uranyl acetate, Magnesium acetate. Sodium R2 - Ammonium thioglycolate, Ammonia. Sodium standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
267	<ol style="list-style-type: none"> 1. Generic Name :TOTAL BILE ACID REAGENT KIT 2. Brand Name :TOTAL BILE ACID REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the detection of Bile acid in serum. 8. Material of Construction: Total Bile acid R1- Goods buffer Oxidized - thio niacinamide urea purine two Thio - NAD. Total Bile acid R2 - Goods buffer NADH 3-HSD 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

268	<ol style="list-style-type: none"> 1. Generic Name :TOTAL BILE ACID (TBA) CALIBRATOR SET 2. Brand Name :TOTAL BILE ACID (TBA) CALIBRATOR SET 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device intended for the preparation of calibration curve for Total Bile Acid (TBA) estimation. 8. Material of Construction: TBA Calibrator, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
269	<ol style="list-style-type: none"> 1. Generic Name :TOTAL BILE ACID (TBA) CONTROL SET 2 LEVELS 2. Brand Name :TOTAL BILE ACID (TBA) CONTROL SET 2 LEVELS 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Total Bile Acid (TBA) Control is an assayed quality control intended for monitoring the precision of laboratory testing procedure of Total Bile Acid (TBA) in human serum. 8. Material of Construction: TBA Control, Diluent 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
270	<ol style="list-style-type: none"> 1. Generic Name :Total iron binding capacity 2. Brand Name :Total iron binding capacity 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Total Iron 8. Material of Construction: TIBC reagent - Acetate Buffer, CTMA Bromide, Cromazurol B. TIBC standard - Tris-HCl, Adenosine, EHSPT 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
271	<ol style="list-style-type: none"> 1. Generic Name :TOTAL PROTEIN KIT 2. Brand Name :TOTAL PROTEIN KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Total Protein in serum or plasma. 8. Material of Construction: TOTAL PROTEIN REAGENT, TOTAL PROTEIN STANDARD 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

272	<ol style="list-style-type: none"> 1. Generic Name :TRANSFERRIN KIT 2. Brand Name :TRANSFERRIN KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Transferrin in human serum 8. Material of Construction: TRANSFERRIN R1 - Buffer Solution) Tris (hydroxymethyl) aminomethane. TRANSFERRIN R2 - Anti serum solution, Anti- human TF anti serum. Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
273	<ol style="list-style-type: none"> 1. Generic Name :TRANSFERRIN KIT (With Calibrator) 2. Brand Name :TRANSFERRIN KIT (With Calibrator) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Transferrin in human serum 8. Material of Construction: TRANSFERRIN R1 - Buffer Solution) Tris (hydroxymethyl) aminomethane. TRANSFERRIN R2 - Anti serum solution, Anti- human TF anti serum. Calibrator 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
274	<ol style="list-style-type: none"> 1. Generic Name :TRIGLYCERIDE KIT (SL) 2. Brand Name :TRIGLYCERIDE KIT (SL) 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of triglycerides in human serum 8. Material of Construction: Triglyceride Reagent, Pipes buffer, TOPS, Potassium ferrocyanate, Magnesium salt, 4-aminoantipyrine, ATP, Lipoprotein, lipase, Glycerol kinase, Glycerol-3-phosphate oxidase Peroxidase Triglycerides Standard Triglyceride standard solution 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
275	<ol style="list-style-type: none"> 1. Generic Name :TRIGLYCERIDES KIT 2. Brand Name :TRIGLYCERIDES KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of triglycerides in serum or plasma. 8. Material of Construction: TRIGLYCERIDES R1, TRIGLYCERIDES R2, TRIGLYCERIDES Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

276	<ol style="list-style-type: none"> 1. Generic Name :UEA-UV (SL) KIT 2. Brand Name :UEA-UV (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Urea U V in human serum 8. Material of Construction: Urea U V Reagent Tris buffer ADP a-ketoglutarate Urease GLDH NADH 2-oxoglutarateUrea U V Standard Urea U V 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
277	<ol style="list-style-type: none"> 1. Generic Name :UREA-B (SL) KIT 2. Brand Name :UREA-B (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Urea in serum, plasma & urine 8. Material of Construction: UREA - B (S.L) R1, UREA - B (S.L) R2, UREA - B (S.L) R3, UREA - B (S.L) Standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
278	<ol style="list-style-type: none"> 1. Generic Name :UREA-B KIT 2. Brand Name :UREA-B KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Urea-B in human serum 8. Material of Construction: Urea-B Reagent Sodium salicylate Sodium nitroprusside Sodium hypochlorite Phosphate buffer Urease Urea-B standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
279	<ol style="list-style-type: none"> 1. Generic Name :UREA-UV KIT 2. Brand Name :UREA-UV KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of Urea-U. V in human serum 8. Material of Construction: Urea-U V Reagent Buffer ADP GLDH Urease NADH Alpha-ketoglutarate 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

280	<ol style="list-style-type: none"> 1. Generic Name :Uric acid 2. Brand Name :Uric acid 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of uric acid in human serum 8. Material of Construction: Uric acid Reagent Phosphate buffer TOPS Amino-4-Antipyrine Uricase Peroxidase Preservatives and stabilizers 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
281	<ol style="list-style-type: none"> 1. Generic Name :URIC ACID (SL) KIT 2. Brand Name :URIC ACID (SL) KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :24 Months 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Device for the quantitative In-Vitro determination of uric acid in human serum 8. Material of Construction: Uric acid Reagent Phosphate buffer TOPS Amino-4-Antipyrine Uricase Peroxidase Preservatives and stabilizers 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
282	<ol style="list-style-type: none"> 1. Generic Name :URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN, BILIRUBIN,GLUCOSE,PROTEIN,SPECIFIC GRAVITY,pH ,BLOOD,ASCORBIC ACID, MICROALBUMIN,CALCIUM AND CREATININE STRIPSUltra Stik, Eco Stik 2. Brand Name :URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN,BILIRUBIN, GLUCOSE,PROTEIN,SPECIFIC GRAVITY,pH ,BLOOD,ASCORBIC ACID,MICROALBUMIN, CALCIUM AND CREATININE STRIPSUltra Stik, Eco Stik 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This pack insert is for ultrastik (Glucose, Bilirubin, Ketone, Specific Gravity,Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Micro albumin)Agappe reagent strips are made for urinalysis both qualitative and semi quantitative which are in vitro reagent for diagnostics. The strips are for professional use only. 8. Material of Construction: Protein, Blood, Glucose, Ketone, Leukocyte, Nitrite, Specific Gravity, Bilirubin, Urobilinogen, Microalbumin 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

283	<p>1. Generic Name :URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN, BILIRUBIN,GLUCOSE,PROTEIN,SPECIFIC GRAVITY,pH ,BLOOD (U-SMART-10 AC)</p> <p>2. Brand Name :URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN,BILIRUBIN, GLUCOSE,PROTEIN,SPECIFIC GRAVITY,pH ,BLOOD (U-SMART-10 AC)</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This pack insert is for ultrastik (Glucose, Bilirubin, Ketone, Specific Gravity,Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Micro albumin)Agappe reagent strips are made for urinalysis both qualitative and semi quantitative which are in vitro reagent for diagnostics. The strips are for professional use only.</p> <p>8. Material of Construction: Protein, Blood, Glucose, Ketone, Leukocyte, Nitrite, Specific Gravity, Bilirubin, Urobilinogen, Microalbumin</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
284	<p>1. Generic Name :URINE GLUCOSE (MRP)STRIPS</p> <p>2. Brand Name :URINE GLUCOSE (MRP)STRIPS</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This pack insert is to be used with product: MRP (Glucose), Urine test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders</p> <p>8. Material of Construction: Glucose oxidase, Peroxidase, Buffer, Non-Reactive Ingredients</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
285	<p>1. Generic Name :URINE STRIP GLUCOSE, KETONE(ECOSTICK)STRIPS</p> <p>2. Brand Name :URINE STRIP GLUCOSE, KETONE(ECOSTICK)STRIPS</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This pack insert is to be used with the following products: MRP (Glucose), Produal(Glucose, Protein), Ketodual (Ketone, Glucose) and Ecostik (Ketone, Glucose &Protein).Urine test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders.</p> <p>8. Material of Construction: Glucose oxidase, Peroxidase, Buffer, Non-Reactive Ingredients</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>

286	<p>1. Generic Name :URINE STRIP GLUCOSE, KETONE(KETODUAL)STRIPS</p> <p>2. Brand Name :URINE STRIP GLUCOSE, KETONE(KETODUAL)STRIPS</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :Urine test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders .Urine Strip Glucose, Ketone (ketodual) Strips is intended for the semi quantitative determination of glucose, ketone in urine.</p> <p>8. Material of Construction: Glucose oxidase, Peroxidase, Buffer, Non-Reactive Ingredients, Sodium Nitroprusside, Buffer, Non-Reactive Ingredients</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
287	<p>1. Generic Name :URINE STRIP GLUCOSE, PROTEIN (PRODUAL STRIPS)</p> <p>2. Brand Name :URINE STRIP GLUCOSE, PROTEIN (PRODUAL STRIPS)</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This pack insert is to be used with the following products: MRP (Glucose), Produal(Glucose, Protein), Ketodual (Ketone, Glucose) and Ecostik (Ketone, Glucose &Protein).Urine test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders.</p> <p>8. Material of Construction: Glucose oxidase, Peroxidase, Buffer, Non-Reactive Ingredients, Tetra bromophenol Blue, Buffer, Non-Reactive Ingredients, Sodium Nitroprusside, Buffer, Non-Reactive Ingredients</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>
288	<p>1. Generic Name :URINE STRIP GLUCOSE, PROTEIN, KETONE, pH and BLOOD(SMART STICK) STRIPS</p> <p>2. Brand Name :URINE STRIP GLUCOSE, PROTEIN, KETONE, pH and BLOOD(SMART STICK) STRIPS</p> <p>3. Notified Category :Other than above substancesImmunology test</p> <p>4. Class of Medical Device :Class B</p> <p>5. Shelf life :2 Years</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :This pack insert is to be used with the following products: MRP (Glucose), Produal(Glucose, Protein), Ketodual (Ketone, Glucose) and Ecostik (Ketone, Glucose &Protein).Urine test strips are used to measure certain constituents in urine which are significant of renal, urinary, hepatic and metabolic disorders.</p> <p>8. Material of Construction: Glucose oxidase, Peroxidase, Buffer, Non-Reactive Ingredients, Tetra bromophenol Blue, Buffer, Non-Reactive Ingredients, Sodium Nitroprusside, Buffer, Non-Reactive Ingredients</p> <p>9. Dimension: NIL</p> <p>10. Model/Catalogue No./Name :NIL</p>

289	<ol style="list-style-type: none"> 1. Generic Name :VITAMIN D REAGENT KIT 2. Brand Name :VITAMIN D REAGENT KIT 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Diagnostic Medical Device for the estimation of Vitamin D in human serum. 8. Material of Construction: Reagent 1 (R1) is buffer and Reagent 2 (R2) is latex particles coated with anti-vitamin D antibodies. 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
290	<ol style="list-style-type: none"> 1. Generic Name :Washing Solution 2. Brand Name :Washing Solution 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Acid wash detergent is intended for cleansing and maintenance of reaction cuvettes and aspiration probes of BiOLis 24i automated clinical analyzer. 8. Material of Construction: Acid solution, Stabilizer, Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
291	<ol style="list-style-type: none"> 1. Generic Name :ACID WASHING SOLUTION (WASHING SOLUTION (Ac) 2. Brand Name :ACID WASHING SOLUTION (WASHING SOLUTION (Ac) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Acid wash detergent is intended for cleansing and maintenance of reaction cuvettes and aspiration probes of BiOLis 24i automated clinical analyzer. 8. Material of Construction: Acid solution Stabilizer and Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
292	<ol style="list-style-type: none"> 1. Generic Name :BASE WASHING SOLUTION (WASHING SOLUTION(AI) 2. Brand Name :BASE WASHING SOLUTION (WASHING SOLUTION(AI) 3. Notified Category :Other than above substancesCleansing solution 4. Class of Medical Device :Class B 5. Shelf life :3 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Alkaline washing detergent intended for cleansing and maintenance of reaction cuvette and aspiration probes of BiOLis 24i automated clinical analyzer. 8. Material of Construction: Alkaline solution (concentrated) Stabilizer Preservative 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL

293	<ol style="list-style-type: none"> 1. Generic Name :ZINC CALIBRATOR 2. Brand Name :ZINC CALIBRATOR 3. Notified Category :Other than above substancesCalibrators/Controls 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This Calibrator is intended for in vitro quantitative determination of ZINC in serum, plasma. 8. Material of Construction: ZINC CALIBRATOR 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
294	<ol style="list-style-type: none"> 1. Generic Name :ZINC Reagent Kit 2. Brand Name :ZINC Reagent Kit 3. Notified Category :Other than above substancesImmunology test 4. Class of Medical Device :Class B 5. Shelf life :2 Years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :This reagent is intended for in vitro quantitative determination of Zinc in serum, plasma & urine. 8. Material of Construction: ZINC reagent R1, ZINC reagent R2, ZINC standard 9. Dimension: NIL 10. Model/Catalogue No./Name :NIL
295	<ol style="list-style-type: none"> 1. Generic Name :Urine Strip Control 2. Brand Name :NIL 3. Notified Category :Other than above substancesReagents/Kits for the antigen detection of infectious agents with a risk of limited propagation 4. Class of Medical Device :Class B 5. Shelf life :2 years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Urine Strip Control is an assayed quality control intended for monitoring the accuracy and precision of urinalysis test procedures for the analytes: Urobilinogen, Bilirubin, Ketone, Blood, Protein, Micro albumin, Nitrite, Leucocytes, Glucose, Specific Gravity & pH 8. Material of Construction: DI water and Chemical ingredients 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
296	<ol style="list-style-type: none"> 1. Generic Name :Cleaner/Rinse For Hematology Anayzer 2. Brand Name :NIL 3. Notified Category :Other than above substancesHematology Reagents/ Kits for estimation of complete blood counts 4. Class of Medical Device :Class A 5. Shelf life :2 years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :To clean the tubes, baths, valves and apertures of Mispa Count X-Hematology analyzer and other Similar hematology analyzers. 8. Material of Construction: Sodium chloride,Sodium sulphate anhydrous ,Buffering agents ,Nonionic surfactant ,Anti fungal & anti bacterial agent , De Ionised water 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

297	<ol style="list-style-type: none"> 1. Generic Name :Diluent for Hematology Analyzer 2. Brand Name :NIL 3. Notified Category :Other than above substancesHematology Reagent Kits for estimation of complete blood count 4. Class of Medical Device :Class A 5. Shelf life :2 years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Used to dilute blood for further testing in Mispa Count X - 3 part Hematology Analyzer and other suitable Hematology analyzers . 8. Material of Construction: Buffering agents,Conductive salts ,Anti fungal&Anti bacterial agent ,De Ionised Water 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
298	<ol style="list-style-type: none"> 1. Generic Name :Lyse For Hematology Analyzer 2. Brand Name :NIL 3. Notified Category :Other than above substances Hematology Reagents/ Kits for estimation of complete blood counts 4. Class of Medical Device :Class A 5. Shelf life :2 years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Used for Lysing of the cells for testing in Mispa Count X - 3 part Hematology Analyzer and other suitable Hematology Analyzers. 8. Material of Construction: Quaternary ammonium salts ,Non-ionic Surfactants ,2-Propanol , De Ionised Water 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
299	<ol style="list-style-type: none"> 1. Generic Name :Deproteinizer for Hematology Analyzer 2. Brand Name :NIL 3. Notified Category :Other than above substancesHematology Reagents/ Kits for estimation of complete blood counts 4. Class of Medical Device :Class A 5. Shelf life :2 years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Final Cleaning and Deproteinising of Mispa Count X -Hematology Analyzer and other suitable Hematology Analyzers . 8. Material of Construction: Proteolytic enzyme,Substrate,Sodium chloride,Buffering agents,Coloring Agent, De Ionised Water 9. Dimension: NA 10. Model/Catalogue No./Name :NIL
300	<ol style="list-style-type: none"> 1. Generic Name :Enzymatic Bilirubin Direct 2. Brand Name :NIL 3. Notified Category :Other than above substancesClinical chemistry Reagent kits for estimation of various parameters 4. Class of Medical Device :Class B 5. Shelf life :2 years 6. Sterile/Non-Sterile:Non-Sterilized 7. Intended Use :Enzymatic Bilirubin Direct Reagent is intended for the quantification of direct Bilirubin in serum and plasma 8. Material of Construction: Enzymatic Bilirubin Direct Reagent 1 (Phthalate Buffer), Enzymatic Bilirubin Direct Reagent 2(Bilirubin Oxidase) 9. Dimension: NA 10. Model/Catalogue No./Name :NIL

301	<ol style="list-style-type: none">1. Generic Name :Enzymatic Bilirubin Total2. Brand Name :NIL3. Notified Category :Other than above substancesClinical chemistry reagents for estimation of various parameters4. Class of Medical Device :Class B5. Shelf life :2 years6. Sterile/Non-Sterile:Non-Sterilized7. Intended Use :Enzymatic Bilirubin Total Reagent is intended for the quantification of Total Bilirubin in serum and plasma8. Material of Construction: Enzymatic Bilirubin Total Reagent 1 (Good's Buffer) , Enzymatic Bilirubin Total Reagent 2 (Bilirubin Oxidase)9. Dimension: NA10. Model/Catalogue No./Name :NIL
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