



REGISTRATION NO. 04721Q10000353

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

URIT Medical Electronic Co., Ltd.

Residence: No.D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P. R. China

Manufacturing Address: No.4 East Alley, Jiuhua Road, Guilin, Guangxi, P. R. China; No.D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P. R. China; Room 102, No.D-02 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P. R. China; Engineering Laboratory Building 3rd Floor, No.D-02 Information Industry District, High-Tech Zone, Guilin

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

Urine Analyzer, Automatic Urine Analyzer, Coagulation Analyzer, Auto Urine Sediment Analyzer, Automated Hematology Analyzer, 5-Part-Diff Auto Hematology Analyzer, Semi-auto Chemistry Analyzer, Automatic Chemistry Analyzer, Uric Acid and Blood Glucose Meter, Hemoglobin Meter, Blood Glucose Meter, Blood Lipid Meter, Electrolyte Analyzer, Integrated Diagnostic System, Microplate Reader, Microplate Washer, Ultrasonic Scaler Tips, Dental Electric Suction Machine, Ultrasonic Periodontal Therapy System, LED Light Curing Device, AI-Libre Urinalysis System, High-Speed Turbine Dental Handpieces, Ultrasonic Scalers, Microplate Reader, Infrared Forehead Thermometer, Medical goggles, Automatic Sample Processing System, and in-vitro diagnostic reagent (Within the scope of the administrative license) (refer to appendix) Design, development, production and service of products.

Date of issue: July 20, 2021

Date of expiry: July 19, 2024

General Manager:

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Appendix

1. **Calibrator for Urine Analysis System(Dry Chemistry)**
2. **Urine reagent Strips**
3. **Urinalysis Control**
4. **Quality Control Solution For Urine Analyzer**
5. **Calibrator Solution for Urine Analyzer**
6. **Medium and Low Positive Concentration Urine Quality Control Products**
7. **Activated Partial Thromboplastin Time(Ellagic Acid Ete) Reagent Kit**
8. **Calibrator for Urine Sediment Analyzer**
9. **Control Material for Urine Sediment Analyzer**
10. **Thrombin Time Reagent Kit**
11. **Prothrombin Time Reagent Kit**
12. **Fibrinogen(Von Clauss) Reagent Kit**
13. **Calibrator for Hematology Analyzer**
14. **Control Material for Hematology Analyzer**
15. **Uric Acid Test Strip (Dry Chemistry)**
16. **Hemoglobin Test Strip**
17. **Hemoglobin Test Strip (Dry Chemistry)**
18. **Hemoglobin Control Solution**
19. **Blood Glucose Test Strip**
20. **Blood Glucose Test Strip (Glucose Oxidase Method)**
21. **Blood Glucose Test Strip (Dry Chemistry)**
22. **Blood Glucose Test Strip (Glucose Dehydrogenase Method)**
23. **Blood Glucose Monitoring System Control Solution**
24. **Electrolyte Analyzer Supporting Reagent (Ion Selective Electrode Method and Pressure Method)**
25. **Electrolyte Analyzer Supporting Reagent (Ion Selective Electrode Method)**
26. **Total Bilirubin Reagent Kit (Vanadate Method)**
27. **Total Bilirubin Reagent Kit(Diazo Salt Method)**
28. **Total Bilirubin Reagent kit (Dichloroaniline Diazo Salt Method)**
29. **Direct Bilirubin Reagent Kit(Diazo Salt Method)**
30. **Direct Bilirubin Reagent Kit (Dichloroaniline Diazo Salt Method)**
31. **Direct Bilirubin Reagent Kit(Vanadate Method)**
32. **Creatinine Reagent Kit(Picrate Acid Method)**
33. **Creatinine Reagent Kit (Creatine Oxidase Method)**
34. **Albumin Reagent Kit (Bromocresol Green Method)**

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35. Creatine Kinase Reagent Kit (Phosphocreatine Substrate Method)
36. Lactate Dehydrogenase Reagent Kit (Lactic Acid Substrate Method)
37. Total Protein Reagent Kit (Biuret Method)
38. Calcium Reagent Kit (OCPC Method)
39. Iron Reagent Kit (Ferrozine Method)
40. Inorganic Phosphorus Reagent Kit (Phosphomolybdate Method)
41. α -Hydroxybutyrate Dehydrogenase Reagent Kit(α -ketobutyric Acid Substrate Method)
42. Alanine Aminotransferase Reagent Kit (Alanine Substrate Method)
43. Urea /BUN Reagent Kit (Urease Continuous Monitoring Method)
44. Cholesterol Reagent Kit (Esterase - Peroxidase Method)
45. γ -Glutamyltransferase Reagent Kit(GCANA Substrate Method)
46. Glucose Reagent Kit(Hexokinase Method)
47. Aspartate Aminotransferase Reagent Kit (Aspartic Acid Substrate Method)
48. Alkaline Phosphatase Reagent Kit (NPP-Kinetic Substrate -AMP Buffer Method)
49. Uric Acid Reagent Kit (Uricase - Peroxidase Method)
50. Glucose Reagent Kit(Oxidase Method)
51. Cholinesterase (CHE) Reagent Kit (Butyryl Thiocholine Substrate Method)
52. α -Amylase Reagent Kit (EPS Substrate Method)
53. Microalbumin Test Kit (Immunoturbidimetric Assay)
54. Apolipoprotein B Reagent Kit (Immunoturbidimetric Assay)
55. Ultrasensitive C-reactive Protein Test Kit(Immunoturbidimetric Assay)
56. Cystatin C Test Kit (Immunoturbidimetric Assay)
57. Prealbumin Test Kit (immunoturbidimetric Assay)
58. β_2 -Microglobulin Test Kit (Immunoturbidimetric Assay)
59. Fructosamine Reagent Kit(NBT Method)
60. Cerebrospinal Fluid/Urine Total Protein Reagent Kit ((Pyrogallol Red Method))
61. Adenosine Deaminase Test Kit (Peroxidase Method)
62. Lipoprotein (a) Test Kit (Immunoturbidimetric Assay)
63. Lipase Reagent Kit (Methyl Resorufin Substrate Method)
64. Transferrin Test Kit (Immunoturbidimetric Assay)
65. Creatine Kinase MB Isoenzymes Reagent Kit (Immunosuppressive method)
66. Lactate Dehydrogenase Isoenzyme 1 Reagent Kit (Chemical Inhibition Method)
67. Low-density Lipoprotein Cholesterol Reagent Kit(Direct Method-Surfactant Removal Method)
68. High-density Lipoprotein Cholesterol Reagent Kit(Direct Method- Selected Suppression Method)
69. Total Bile Acid Reagent Kit(Enzymatic Cycling Method)

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70. Triglycerides Reagent Kit(Enzymatic Method)
71. Magnesium Reagent Kit(Calmagite Method)
72. Antistreptolysin O Test Kit (Immunoturbidimetric Assay)
73. Rheumatoid factor Protein Test Kit (Immunoturbidimetric Assay)
74. Apolipoprotein A1 Reagent Kit(Immunoturbidimetric Assay)
75. Carbon Dioxide Reagent Kit (PEPC Enzymatic Method)
76. Conventional Biochemical Multiple Compound Calibrator
77. Conventional Biochemical Multiple Compound Quality Control Serum.
78. Pancreatic Amylase Reagent Kit (EPS Substrate Method)
79. Immunoglobulin M Test Kit (Immunoturbidimetric Assay)
80. C-Reactive Protein Test Kit(Immunoturbidimetric Assay)
81. Immunoglobulin A Test Kit (Immunoturbidimetric Assay)
82. Immunoglobulin G Test Kit (Immunoturbidimetric Assay)
83. Complement C3 Test Kit (Immunoturbidimetric Assay)
84. Complement C4 Test Kit (Immunoturbidimetric Assay)
85. Detergent
86. Alkaline Detergent for Chemistry Analyzer
87. Sheath
88. Lyse
89. Diluent
90. Staining solution for Hematology Analyzer
91. Buffer
92. Dewax
93. Tissue Fixation Solution
94. Sheath for Urine Analysis
95. C-Reactive Protein Test Kit(Immunoturbidimetric Assay)
96. Full Range C-Reactive Protein Test Kit (Latex-Enhanced Immunoturbidimetric Assay)
97. Zinc Reagent Kit (PAPS Method)
98. Homocysteine (HCY) Reagent Kit(Enzymatic Cycling Method)
99. Hematoxylin
100. Eosin
101. C-Reactive Protein Control
102. C-Reactive Protein Calibrator
103. Ammonia (AMM) Test kit (Glutamate dehydrogenase Assay)

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- 104. Leucineaminopeptidase (LAP) Test Kit (L-Leucine p-nitroanilide hydrochloride substrate Assay)
- 105. Retinol Binding Protein (RBP) Test Kit (Latex Enhanced Immunoturbidimetric Assay)
- 106. Sialic acid (SA) Test Kit (Enzymatic Method)
- 107. Urinary transferrin (UTF) Test Kit (Immunoturbidimetric Assay)
- 108. Monoamine Oxidase (MAO) Test Kit (Continuous Monitoring Method)
- 109. Angiotensin Converting Enzyme (ACE) Test Kit (FAPGG substrate method)
- 110. D-3-Hydroxybutyrate (D3-H) Test Kit (D-3-Hydroxybutyrate Dehydrogenase Assay)
- 111. 5' -Nucleotidase(5' -NT) Test Kit (Peroxidase Assay)
- 112. N-Acetyl- β -D-Glucosaminidase (NAG) Test Kit (MPT Method)
- 113. Lactate (LAC) Test Kit (Lactate oxidase method)
- 114. Plaque indicator
- 115. Wright-Giemsa Stain
- 116. CD3 FITC
- 117. CD45 PerCP-Cy5.5

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