

REGISTRATION NO. 04718Q10000301-2

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

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, Portable Urine Analyzer, Coagulation Analyzer, Auto Urine Sediment Analyzer, Automated Hematology Analyzer, 5-Part-Diff Auto Hematology Analyzer, Semi-auto Chemistry Analyzer, Chemistry Analyzer, Automatic Chemistry Analyzer, Uric Acid and Blood Glucose Meter, Hemoglobin Meter, Blood Glucose Meter, Mobile Blood Glucose Meter, Blood Lipid Meter, Electrolyte Analyzer, Integrated Diagnostic System, Microplate Reader, Otoscope, Direct Ophthalmoscopes, Microplate Washer, Percussion Hammer, Ultrasonic Scaler Tips, Dental Electric Suction Machine, Ultrasonic Periodontal Therapy System, LED Curing Light, and in-vitro diagnostic reagent (See the Attached) Design, development, production and service of products.

Date of issue: July 20, 2018

Date of expiry: July 19, 2021

Date of change: September 09, 2019

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

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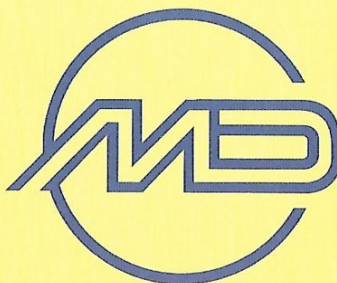
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Annex:

1. Calibration of Urine (Dry Chemistry) Analysis System
2. Urine Reagent Strips
3. Urine Reagent Strips
4. Urinalysis Control
5. Quality Control Solution For Urine Analyzer
6. Calibrator Solution for Urine Analyzer
7. Medium and Low Positive Concentration Urine Quality Control Products
8. Activated Partial Thromboplastin Time(Ellagic Acid Ete) Reagent Kit
9. Calibrator for Urine Sediment Analyzer
10. Control Material for Urine Sediment Analyzer
11. Thrombin Time Reagent Kit
12. Prothrombin Time Reagent Kit
13. Fibrinogen(Von Clauss) Reagent Kit
14. Calibrator for Hematology Analyzer
15. Control Material for Hematology Analyzer
16. Uric Acid Test Strip
17. Hemoglobin Test Strips
18. Hemoglobin Control Solution
19. Blood Glucose Test Strips
20. Blood Glucose Test Strips (Glucose oxidase method)
21. Blood Glucose Test Strips (Glucose dehydrogenase method)
22. Blood Glucose Monitoring System Control Solution
23. Cholesterol Test Strip
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)

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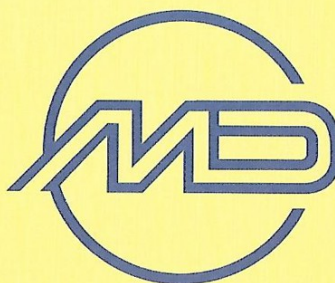
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Annex:

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)
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 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)

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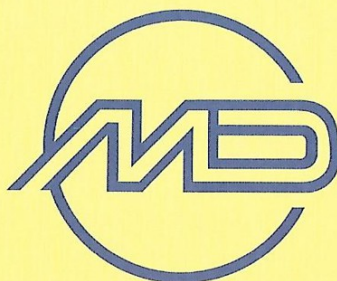
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60. Cerebrospinal Fluid/Urine Total Protein Reagent Kit ((Pyrogallol Red Method)
61. Adenosine Deaminase Test Kit (Peroxidase Method)
62. Lipoprotein (a) Test Kit (Immunoturbidimetric Assay)
63. Lipase Reagent Kit (Methyl Resorufin Substrate Method)
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)
70. Triglycerides Reagent Kit(Enzymatic Method)
71. Magnesium Reagent Kit(Calmagite Method)
72. Antistreptolysin O Test Kit (Immunoturbidimetric Assay)
73. Rheumatoid factor 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. Sheath
87. Lyse

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Annex:

- 88. Diluent
- 89. Staining solution for Hematology Analyzer
- 90. Buffer
- 91. Dewax
- 92. Tissue Fixation Solution
- 93. Sheath for Urine Analysis
- 94. CRP kit(latex immunoturbidimetric method)
- 95. Urine Reagent Strips
- 96. Zinc Reagent Kit (PAPS Method)
- 97. Homocysteine (HCY) Reagent Kit(Enzymatic Cycling Method)
- 98. Hematoxylin staining solution
- 99. Eosin Staining Solution

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