



Registration No. 04724Q10426R6M

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that:

URIT Medical Electronic Co., Ltd.

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

Manufacturing address: NO.4 East Alley, Jiuhua Road, 541001 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA; No.D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China; No. D-02, Information Industry District, High-tech Zone, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA; 1F & 2F of Building No. 1, Building No. 2, No. GX-G08, East Side of Donghuan Road, Qixing District, 541004 Guilin Guangxi, PEOPLE'S REPUBLIC OF CHINA

Operates a Quality Management System which complies with the requirements of:

GB/T 19001-2016 idt ISO 9001:2015

For the following scope:

Design development, production, and service of the products included in the attachment.

Date of issue: July 20, 2024

Date of expiry: July 19, 2027

General manager:

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



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管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information is available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993



Attachment:

I. Instrumentation and Equipment

1. Urine Analyzer
2. Automatic Urine Analyzer
3. Coagulation Analyzer
4. Auto Urine Sediment Analyzer
5. Automated Hematology Analyzer
6. 5-Part-Diff Auto Hematology Analyzer
7. Semi-auto Chemistry Analyzer
8. Automatic Chemistry Analyzer
9. Uric Acid and Blood Glucose Meter
10. Hemoglobin Meter
11. Blood Glucose Meter
12. Blood Lipid Analyzer
13. Electrolyte Analyzer
14. Integrated Diagnostic System
15. Microplate Reader
16. Microplate Washer
17. Automatic Urine Analyzer(SG module)
18. U-temperature logger
19. Veterinary Urine Analyzer
20. Domestic Oxygenator
21. AI-Libre Urinalysis System
22. Automated Veterinary Hematology Analyzer
23. Infrared Forehead Thermometer
24. Automatic sample processing system
25. OraSeal Caulking & Blocking-out Putty
26. Caries Indicator
27. Caries Indicator Strips
28. Immersion Oils
29. Flow Cytometer
30. Uric Acid Meter
31. Blood Glucose / Uric Acid / Cholesterol Meter
32. Automatic Immunoassay Analyzer
33. Automated Independent Temperature-controlled Immunohistochemistry and H&E Single Drop Stainer
34. Automatic sample post-processing system

35. Oxygen Concentrator

36. Blood Glucose, Uric Acid and Ketone Meter
37. Semi-auto Veterinary Coagulation Analyzer
38. Automatic Veterinary Urine Analysis System
39. Blood Glucose and Ketone Meter
40. Dry Biochemical Analyzer
41. Medical Magnifier

II. Reagents

(A) Medical Device Products : In Vitro Diagnostic Reagents (within the scope of administrative approval)

(B) Non-Medical Device Products

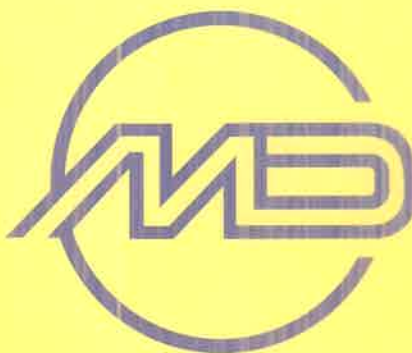
1. Detergent
2. Probe Cleaner
3. Lytic Reagent
4. Diluent
5. Veterinary Urine reagent Strips
6. Maintenance agent for Urine Analyzer
7. Sheath
8. Lyse
9. Focusing Fluid for Urine Sediment Analyzer
10. DI Probe Cleaner
11. Rinse Kit
12. Electrolyte Analyzer Maintenance Solution
13. Oral Analysis Reagent Strips
14. Reagent For Automatic Slidemake Stainer
15. Chlorhexidine gargle
16. Calibrator for Veterinary Urine Analysis
17. Control Material for Veterinary Urine Analysis
18. CRP Monoclonal Antibody/SAA Monoclonal Antibody
19. Staining solution for Veterinary Hematology Analyzer
20. Dairy Cow Blood Ketones Test Strip
21. Urinalysis Control
22. Animal Aspartate Aminotransferase Reagent Kit (Aspartic Acid Substrate Method)
23. Animal Alanine Aminotransferase Reagent Kit



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| (Alanine Substrate Method) | Method) |
| 24. Animal Albumin Reagent Kit (Bromocresol Green Method) | 44. Animal Cholesterol Reagent Kit (Esterase - Peroxidase Method) |
| 25. Animal Total Protein Reagent Kit (Biuret Method) | 45. Animal High-density Lipoprotein Cholesterol Reagent Kit (Direct Method- Selected Suppression Method) |
| 26. Animal Total Bilirubin Reagent kit (Dichloroaniline Diazo Salt Method) | 46. Animal Low-density Lipoprotein Cholesterol Reagent Kit (Direct Method-Surfactant Removal Method) |
| 27. Animal Direct Bilirubin Reagent Kit (Dichloroaniline Diazo Salt Method) | 47. Animal Calcium Reagent Kit (OCPC Method) |
| 28. Animal Alkaline Phosphatase Reagent Kit (NPP-Kinetic Substrate -AMP Buffer Method) | 48. Animal Inorganic Phosphorus Reagent Kit (Phosphomolybdate Method) |
| 29. Animal γ -Glutamyltransferase Reagent Kit (GCANA Substrate Method) | 49. Animal Lactate (LAC) Test Kit (Lactate oxidase method) |
| 30. Animal Total Bile Acid Reagent Kit (Enzymatic Cycling Method) | 50. Animal Lipase Test Kit (Methoxyresorufin substrate method) |
| 31. Animal Ammonia (AMM) Test kit (Glutamate dehydrogenase Assay) | 51. Animal Multiple biochemical calibrators |
| 32. Animal Cholinesterase (CHE) Test Kit (Butyryl Thiocoline Substrate Method) | 52. Monoamine Oxidase Reagent Material |
| 33. Animal Creatinine Reagent Kit (Creatine Oxidase Method) | |
| 34. Animal Urea /BUN Reagent Kit (Urease Continuous Monitoring Method) | |
| 35. Animal Uric Acid Reagent Kit (Uricase - Peroxidase Method) | |
| 36. Animal Carbon Dioxide Reagent Kit (PEPC Enzymatic Method) | |
| 37. Animal α -Amylase Reagent Kit (EPS Substrate Method) | |
| 38. Animal Pancreatic Amylase Reagent Kit (EPS Substrate Method) | |
| 39. Animal Creatine Kinase Reagent Kit (Phosphocreatine Substrate Method) | |
| 40. Animal Lactate Dehydrogenase Reagent Kit (Lactic Acid Substrate Method) | |
| 41. Animal α -Hydroxybutyrate Dehydrogenase Reagent Kit (α -ketobutyric Acid Substrate Method) | |
| 42. Animal Glucose Reagent Kit (Oxidase Method) | |
| 43. Animal Triglycerides Reagent Kit (Enzymatic | |



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