Registration No. 04724Q10000426

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

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: 1. No.4 East Alley, Jiuhua Road, 541001 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA; 2. No.D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China; 3. No. D-02, Information Industry District, High-tech Zone, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA; 4. 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 42061-2022 / ISO 13485:2016

Medical devices-Quality management systems-Requirements for regulatory purposes

For the following scope:

See the attached page for product design, development, production and service.

Date of issue: July 20, 2024

Date of expiry: July 19, 2027

Date of change: July 02, 2026

General manager:

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

Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

Registration No. 04724Q10000426

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. U-temperature logger
18. Veterinary Urine Analyzer
19. Domestic Oxygenerator,
20. AI-Libre Urinalysis System
21. Automated Veterinary Hematology Analyzer
22. Automatic sample processing system
23. OraSeal Caulking & Blocking-out Putty
24. Caries Indicator
25. Caries Indicator Strips
26. Immersion Oils
27. Flow Cytometer

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

Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

Registration No. 04724Q10000426

Attachment:

28. Uric Acid Meter
29. Blood Glucose / Uric Acid / Cholesterol Meter
30. Chemiluminescence Immunoassay Analyzer
31. Fully Automated Special and Individual Dispensing H&E Stainer
32. Automatic sample post-processing system
33. Oxygen Concentrator
34. Blood Glucose, Uric Acid and Ketone Meter
35. Semi-auto Veterinary Coagulation Analyzer
36. Automatic Veterinary Urine Analysis System
37. Blood Glucose and Ketone Meter
38. Dry Biochemical Analyzer
39. Medical Magnifier
40. Slide Maker and Stainer
41. Veterinary Automatic Hematology Analyzer
42. Veterinary Intensive Care Chamber
43. Veterinary Dry Chemistry Biochemical Analyzer
44. Vaginal Secretion Dry Chemistry Analyzer
45. Automatic Vaginal Secretion Analysis System
46. Specific Protein Analyzer
47. Automatic Coagulation Analyzer
48. Sample Preparation System
49. Blood Glucose/Uric Acid/Blood ketone Meter
50. Blood glucose data management software
51. Disposable peripheral blood collection tubes
52. Microscopic Slide for Vaginal Secretion Morphology
53. Multifunctional Morphological Analyze
54. Concentrated Reagent Dilute
55. Smart terminal Mini

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

Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

Registration No. 04724Q10000426

Attachment:

II、Reagents：

（1）Medical Device Products：

1、In Vitro Diagnostic Reagents (within the scope of administrative approval)

（2）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. Electrolyte Analyzer Maintenance Solution
12. Rinse Kit
13. Oral Analysis Reagent Strips
14. Reagent For Automatic Slidemaker 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. Veterinary Aspartate Aminotransferase Reagent Kit (Aspartic Acid Substrate Method)
23. Veterinary Alanine Aminotransferase Reagent Kit (Alanine Substrate Method)
24. Veterinary Albumin Reagent Kit (Bromocresol Green Method)

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

Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

Registration No. 04724Q10000426

Attachment:

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

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

Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

Registration No. 04724Q10000426

Attachment:

51. Veterinary Multiple biochemical calibrators
52. Monoamine Oxidase Reagent Material
53. Differentiation solution
54. Cell Fix Solution
55. Veterinary Hematology Control
56. Veterinary Hematology Calibrator
57. Veterinary Electrolyte Analyzer Supporting Reagent(Ion Selective Electrode Method and Pressure Method)
58. Alkaline Detergent for Chemistry Analyzer materials
59. Multiple biochemical calibrators materials
60. Multiple compound quality control products for biochemical immunity materials
61. Glycated albumin reagent materials

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

Note: Only certified organizations have received regular supervision audits and resulted in compliance, the certificates would remain valid. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No. A88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993