

URIT®



桂林优利特医疗电子有限公司

URIT MEDICAL ELECTRONIC CO., LTD.

地址: 中国广西桂林高新区信息产业园D-07号 邮编: 541004
ADD: No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R. China
电话: +86 773 2288583 传真: +86 773 2288560 E-MAIL: export@uritest.com
TEL: +86 773 2288583 FAX: +86 773 2288560 HTTP://www.urit.com



EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer: **URIT Medical Electronic Co., Ltd.**

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

The EC Declaration of Conformity is valid for the following products:
SEE ATTACHMENT

Category: OTHER IVD

Conformity assessment route:

This declaration of conformity is based on the European In Vitro Diagnostics Medical Device Directive 98/79/EC, Annex III.

Applicable Standards:

EN 61010-2-101: 2002, EN 61010-2-101, EN 61010-1: 2010, EN 61326-2-6: 2013,
EN 61326-1: 2013, EN 61000-3-2: 2014, EN 61000-3-3: 2013, EN 61326-2-6: 2006,
EN 61010-2-101: 2017, EN 61000-3-2: 2006+A1: 2009+A2: 2009& EN61000-3-3:2008,
EN ISO 18113-2, EN ISO13485: 2016, EN 375, EN 640, EN ISO 18113-1: 2011, EN 18113-3: 2011,
EN 15223-1: 2016, EN ISO 14971: 2007, EN591: 2001.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

We hereby appoint Wellkang Ltd(www.CE-marking.eu), Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, N. Ireland to act as our European Authorized Representative as explicitly defined in the aforementioned Directive.

Signed on April 18, 2021
Represented by

Place: Guilin, Guangxi, China.

Signature

Name of authorized signatory: Shi Ping
Position held in the company: President

Seal/Stamp:



Product/s:	Model:
Urine Analyzer	URIT-50, URIT-180, URIT-500B, URIT-500C, URIT-330, URIT-31, URIT-560
Automatic Urine Analyzer	URIT-1600, UC-1800
Detergent for Automatic Urine Analyzer	URIT D 12, URIT D 21N, URIT D 22
Auto Urine Sediment Analyzer	URIT-1280, URIT-1000Plus, UD-1320
Urine Reagent Strips	URIT 1V ^K , URIT 1V ^P , URIT 1V ^G , URIT 2V ^{GK} , URIT 2V ^{PG} , URIT 3V ^{PGp} , URIT 4V ^{PGpSP} , URIT 5V, URIT 9V, URIT 10V, URIT 11V, URIT 10G, URIT 11G, URIT 14G, URIT 11F, URIT 12F, URIT 14F, URIT 11FA, URIT 12FA, URIT 14FA, URIT 10E
Detergent A	URIT D11
Detergent B	URIT D13
Detergent C	URIT D14
Detergent	URIT D16
Sheath for Urine Analyzer	URIT S11
Maintenance agent for Urine Analyzer	URIT D 22
Calibrator Solution For Urine Analyzer	URIT YC 2 ST
Quality Control Solution For Urine Analyzer	URIT YQ 3 ^{STC}
Calibrator for Urine Sediment Analyzer	URIT CA 21
Control Material for Urine Sediment	URIT QC 22
Urinalysis Control	UQ-14, UQ-13, UQ-11, UQ-10
Focusing Fluid for Urine Sediment Analyzer	URIT FC23
Automated Hematology Analyzer	URIT-3000Plus, URIT-2900Plus, URIT-3020, URIT-3060
DI Probe Cleaner	URIT D48
Probe Cleaner	URIT D43
Diluent	URIT D31
Lytic Reagent	URIT L21
Detergent	URIT D41
5-Part-Diff Auto Hematology Analyzer	URIT-5500, URIT-5250, URIT-5160, URIT-5380
Lyse	URIT 5L 11
Diluent	URIT 5D 11
Sheath	URIT 5S 11
Detergent	URIT D46
Staining solution for hematology analyzer	URIT R 11
Control Material for Hematology Analyzer	URIT QC 11
HQ-3DIFF Control Material for Hematology Analyzer	HQ-3DIFF
HQ-5DIFF Control Material for Hematology Analyzer	HQ-5DIFF
HQ-CAL Calibrator for Hematology Analyzer	HQ-CAL



Product/s:	Model:
Automatic Chemistry Analyzer	URIT-8280, URIT-8260, URIT-8021A, URIT-8031, URIT-8210, URIT-8460, URIT-8400
Chemistry Analyzer	URIT-810, URIT-880
Albumin Reagent Kit (Bromcresol Green Method)	ALB
Alkanline Phosphatase Reagent Kit (NPP-Kinetic Substrate-AMP Buffer Method)	ALP
Alanine Aminotransferase Reagent Kit (Alanine Substrate Method)	ALT
Amylase Reagent Kit (EPS Substrate Method)	α -AMY
Aspartate Aminotransferase Reagent Kit (Aspartic Acid Substrate Method)	AST
Calcium Reagent Kit (OCPC Method)	Ca
Cholinesterase Reagent Kit (Butyryl Thiocholine Substrate Method)	CHE
Creatine Kinase Reagent Kit (Phosphocreatine Substrate Method)	CK-NAC
Creatinine Reagent Kit (Picrate Acid Method)	Cr
Direct Bilirubin Reagent Kit(Diazo Salt Method)	DB
Iron Reagent Kit (Ferrozine Method)	Fe
γ -Glutamyltransferase Reagent Kit (GCANA Substrate Method)	GGT
Glucose Reagent Kit (Hexokinase Method)	GLU-HK
Glucose Reagent Kit(Oxidase Method)	GLU-OX
High-density Lipoprotein Cholesterol Reagent Kit(Direct Method- Selected Suppression Method)	HDL-C
Lactate Dehydrogenase Reagent Kit (Lactic Acid Substrate Method)	LDH
Low-density Lipoprotein Cholesterol Reagent Kit (Direct Method-Surfactant Removal Method)	LDL-C
Magnesium Reagent Kit (Calmagite Method)	Mg
Inorganic Phosphorus Reagent Kit (Phosphomolybdate Method)	P
Total Bilirubin Reagent Kit (Vanadate Method)	TB-VA
Total Bilirubin Reagent Kit(Diazo Salt Method)	TB
Total Bile Acid Reagent Kit(Enzymatic Cycling Method)	TBA
Triglycerides Reagent Kit(Enzymatic Method)	TG
Total Protein Reagent Kit (Biuret Method)	TP
Uric Acid Reagent Kit (Uricase - Peroxidase Method)	UA
Urea /BUN Reagent Kit (Urease Continuous Monitoring Method)	Urea
α -Hydroxybutyrate Dehydrogenase Reagent Kit (α -ketobutyric Acid Substrate Method)	α -HBDH
Cholesterol Reagent Kit(Esterase - Peroxidase Method)	CHOL
Alkaline Detergent for Chemistry Analyzer	URIT DC1



Product/s:	Model:
Homocysteine (HCY) Reagent Kit (Enzymatic Cycling Method)	HCY
Full Range C-Reactive Protein Test Kit (Latex-Enhanced Immunoturbidimetric Assay)	FR-CRP
Uric Acid Reagent Kit (Uricase - Peroxidase Method)	UA
Prealbumin Test Kit (immunoturbidimetric Assay)	PA
Total Bilirubin Reagent kit (Dichloroaniline Diazo Salt Method)	TB-DCA
Direct Bilirubin Reagent Kit (Dichloroaniline Diazo Salt Method)	DB-DCA
Creatinine Reagent Kit (Creatine Oxidase Method)	CR-OX
β 2-Microglobulin Test Kit (Immunoturbidimetric Assay)	β 2-MG
Microalbumin Test Kit (Immunoturbidimetric Assay)	MALB
Ultrasensitive C-reactive Protein Test Kit (Immunoturbidimetric Assay)	HCRP
Lactate Dehydrogenase Isoenzyme 1 Reagent Kit (Chemical Inhibition Method)	LDH1
Lipoprotein (a) Test Kit (Immunoturbidimetric Assay)	Lp(a)
C-Reactive Protein Test Kit (Immunoturbidimetric Assay)	CRP
Pancreatic Amylase Reagent Kit (EPS Substrate Method)	PAMY
Transferrin Test Kit (Immunoturbidimetric Assay)	TF
Microplate Reader	URIT-660
Microplate washer	URIT-670
Coagulation Analyzer	URIT-610, URIT-600
Standard Solution A	URIT A
Standard Solution B	URIT B
Electrode Cleaning Solution	URIT F
Internal Filling Solution (for common use)	URIT G-2
Internal Filling Solution (for reference use)	URIT G-1
Calibration Solution	URIT C
Active Solution	URIT D
Electrolyte Analyzer Supporting Reagent	Reagent Kit I, Reagent Kit II
Hemoglobin Meter	URIT-12, PH-01, PH-01A
Hemoglobin Test Strip	H12, PH 01
Hemoglobin Control Solution	HQ-A





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.**

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (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



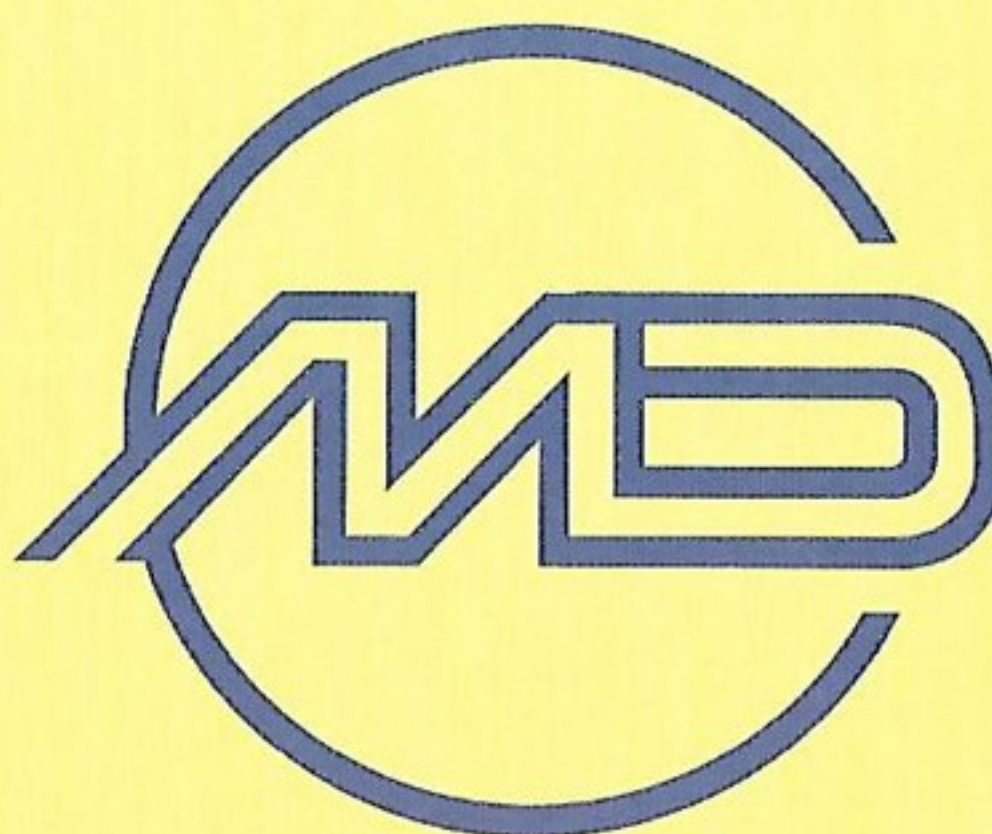
REGISTRATION NO. 04718Q10000301-2

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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REGISTRATION NO. 04718Q10000301-2

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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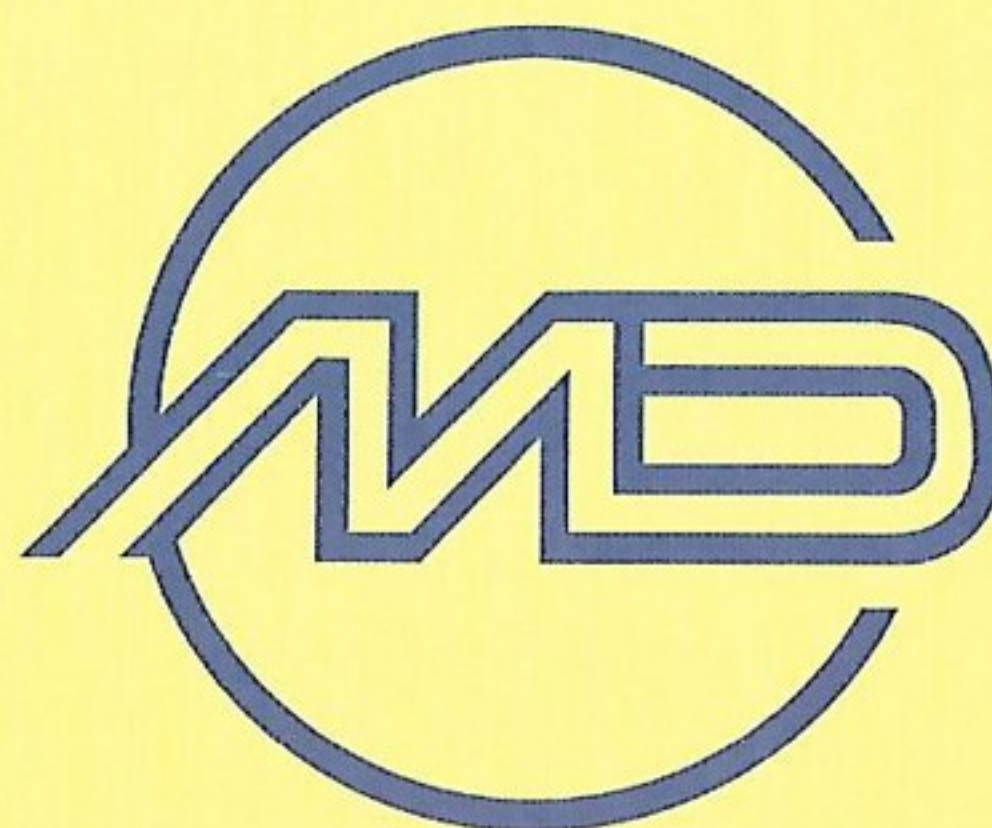
REGISTRATION NO. 04718Q10000301-2

Annex:

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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REGISTRATION NO. 04718Q10000301-2

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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REGISTRATION NO.04718Q10259R4M-2

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

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)

GB/T 19001-2016 idt ISO 9001:2015

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, Otolaryngoscope, Direct Ophthalmoscopes, Microplate Washer, Percussion Hammer, URIT-800Vet, URIT-880Vet Semi-automatic Chemistry Analyzer, URIT-8021AVet Automatic Chemistry Analyzer, Automatic Urine Analyzer (SG module), U-temperature logger, URIT-150Vet Urine Analyzer, URIT-50Vet Urine Analyzer, URIT-30Vet Urine Analyzer, URIT-31Vet Urine Analyzer, Ultrasonic Scaler Tips, Dental Electric Suction Machine, Ultrasonic Periodontal Therapy System, LED Curing Light, Domestic oxygenator, Lytic Reagent, Diluent, URIT 11Vet Urine Reagent Strips, Maintenance agent for Urine Analyzer, Sheath, Detergent, Lyse, Diluent, Focusing Fluid for Urine Sediment Analyzer, DI Probe Cleaner, URIT-910 Series Electrolyte Analyzer Maintenance Solution (URIT D/URIT F), Rinse Kit, Probe Cleaner and in-vitro diagnostic reagent (See the Attached) Design, development, production and service of products.

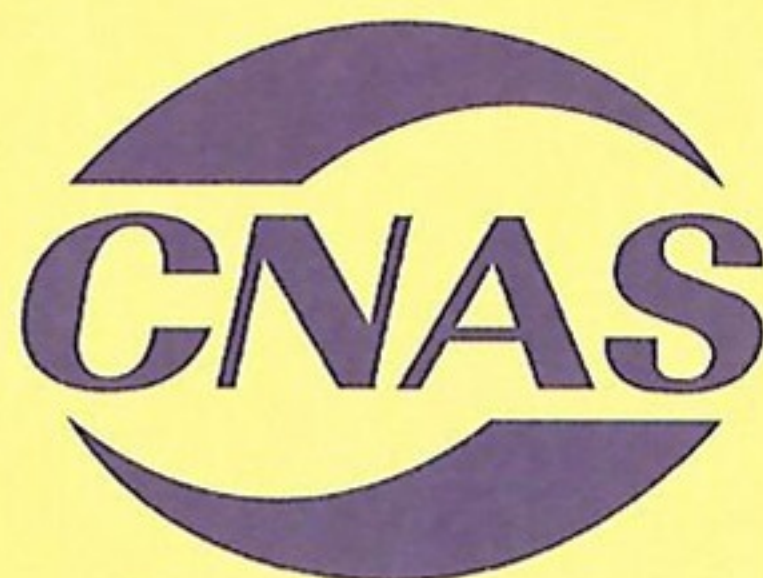
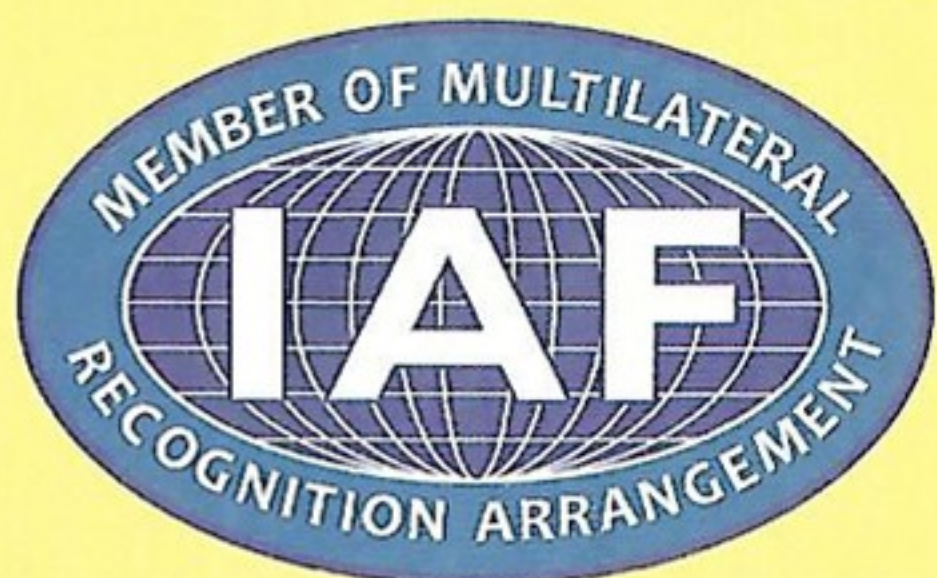
Date of issue: July 20, 2018

Date of expiry: July 19, 2021

Date of change: September 09, 2019

General Manager:

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



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

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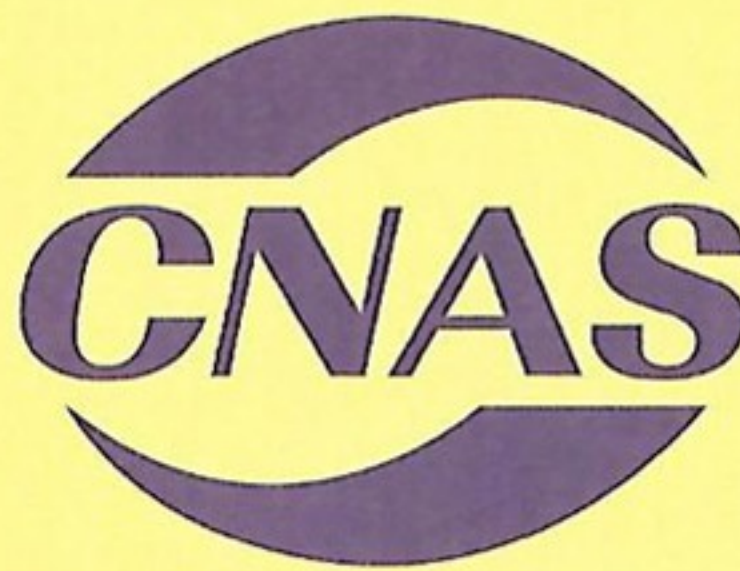
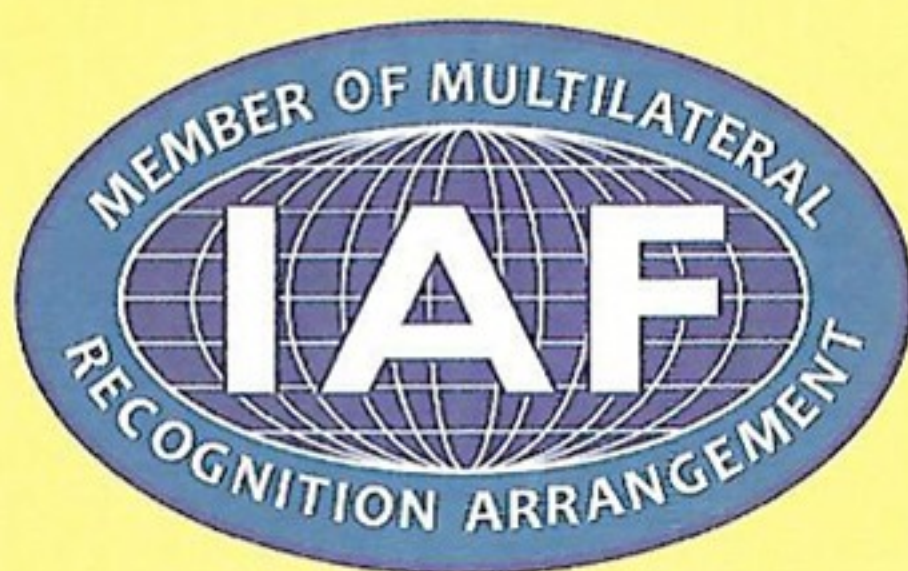


REGISTRATION NO.04718Q10259R4M-2

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)

**BEIJING HUA GUANG CERTIFICATION
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中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

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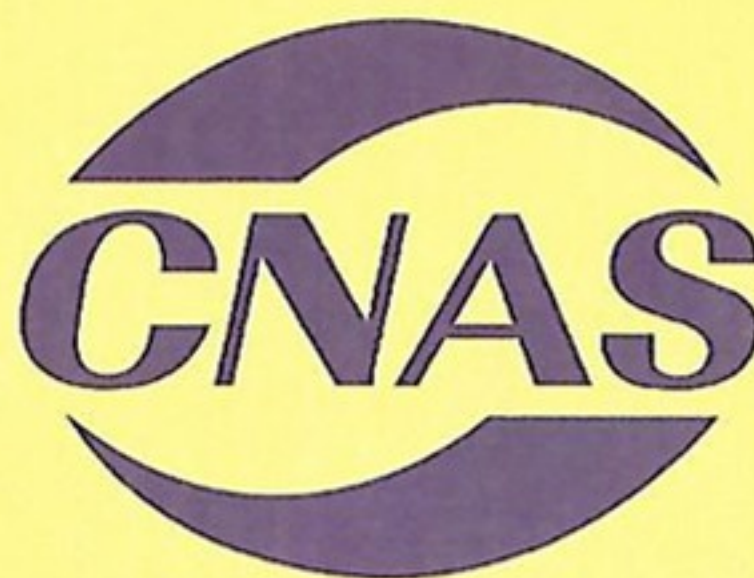
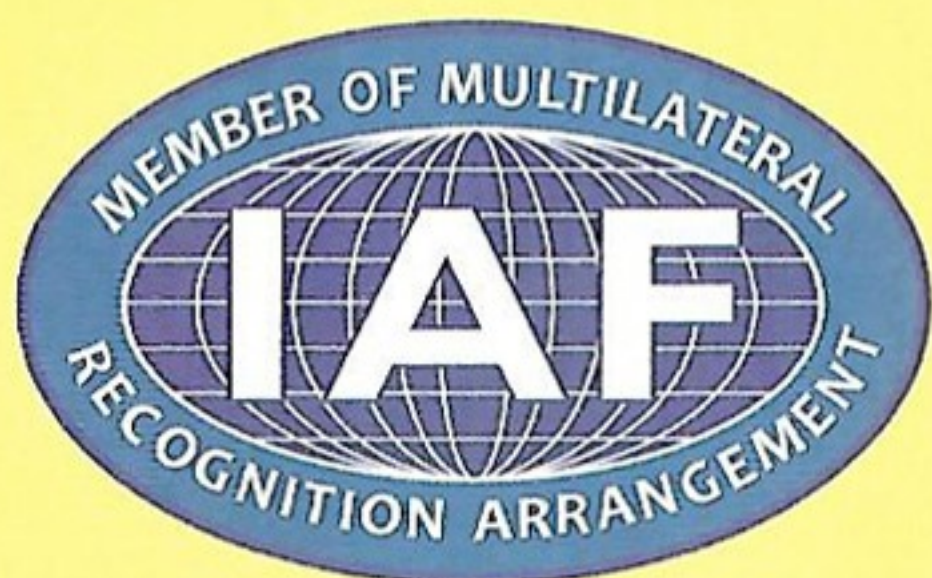


REGISTRATION NO.04718Q10259R4M-2

Annex:

30. Direct Bilirubin Reagent Kit (Dichloroaniline Diazo Salt Method)
31. Direct Bilirubin Reagent Kit (Vanadate Method)
32. Creatinine Reagent Kit (Picric 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 Thiocoline 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)

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



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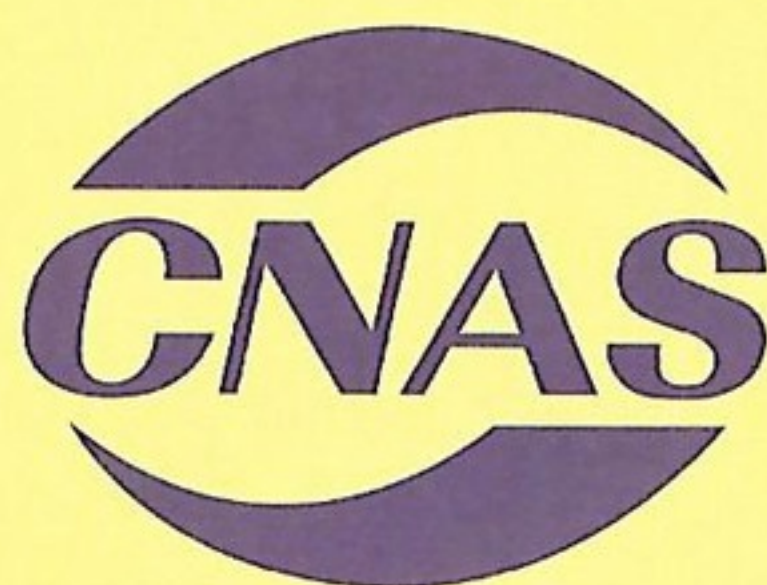
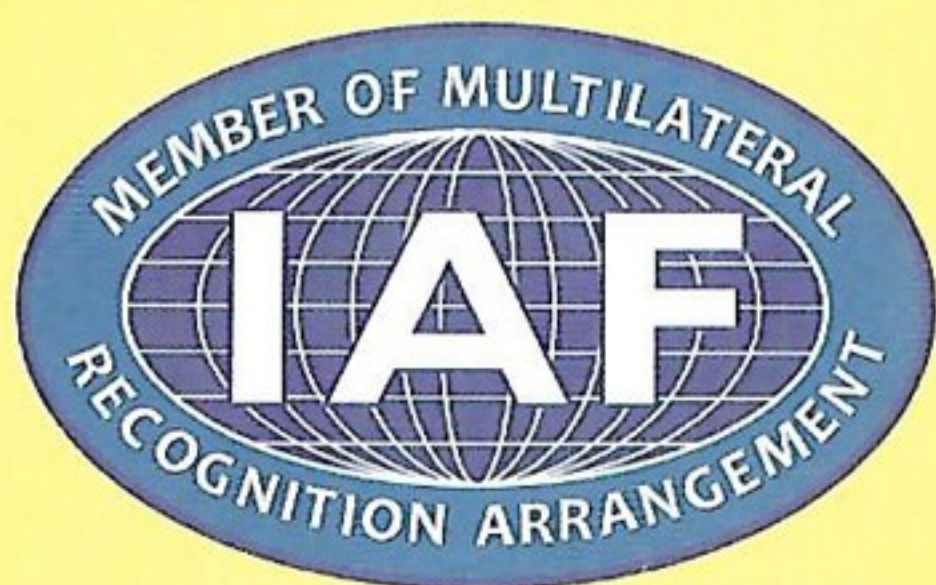


REGISTRATION NO.04718Q10259R4M-2

Annex:

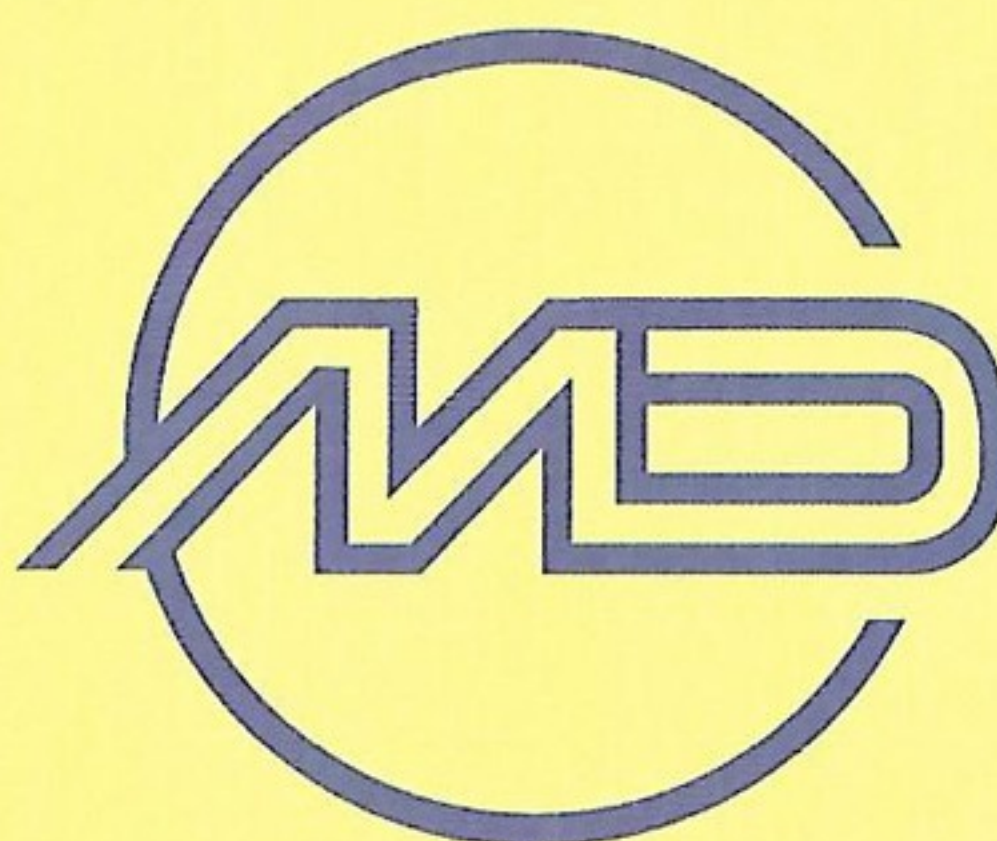
60. Cerebrospinal Fluid/Urine Total Protein Reagent Kit ((Pyrogallol Red Method)
61. Adenosine Deaminase Test Kit (Peroxidase Method)
62. Lipoprotein (a) Test Kit (Immunoturbidimetric Assay)
63. Lipase Reagent Kit (Methyl Resorufin Substrate Method)
64. Transferrin Test Kit (Immunoturbidimetric Assay)
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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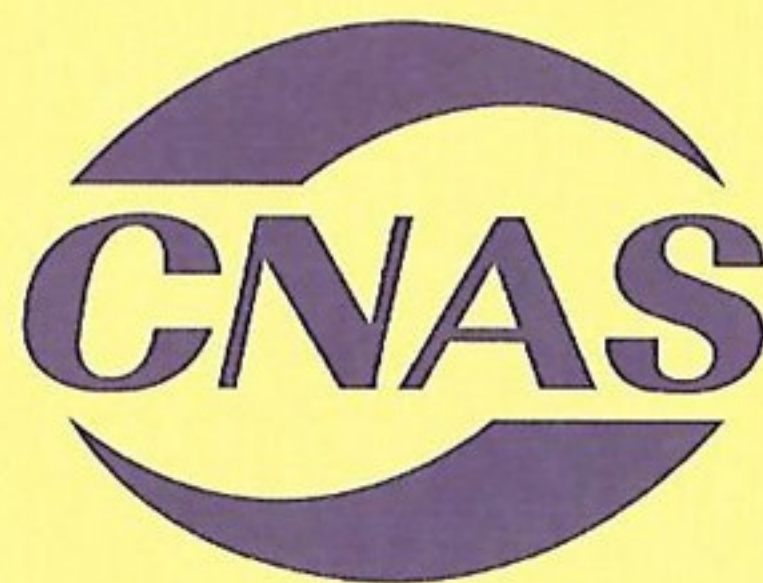
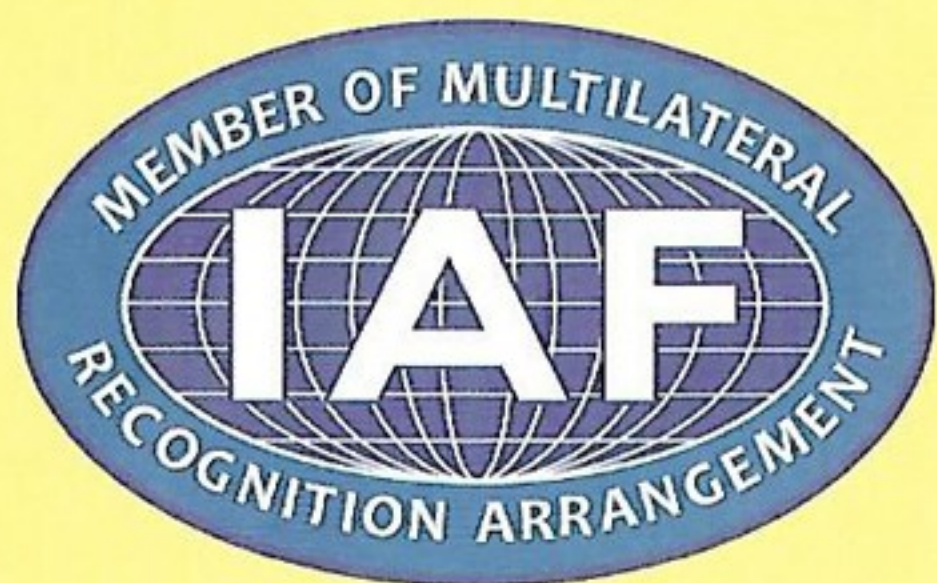


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Annex:

- 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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