

URIT



桂林优利特医疗电子有限公司

URIT MEDICAL ELECTRONIC CO., LTD.

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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 61326-1:2006, EN 61000-3-2:2006 + A1:2009, EN 61000-3-3:2008,

EN 61010-1:2010, EN 61010-2-101:2002,

EN ISO 18113-1:2011, EN 18113-3:2011, EN 15223-1:2016, EN 13612:2002+AC: 2002,

EN ISO 23640:2015,

EN ISO 13485:2016, EN ISO 14971:2012, EN 61326-2-6:2013, EN 61000-3-2:2014, EN 61000-3-3:2013, EN 61326-2-6:2006, EN 61010-1:2001

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 t/a Wellkang Tech Consulting, Suit B, 29 Harley Street, London W1G 9QR, UK** to act as our European Authorized Representative, as explicitly defined in the aforementioned Directive.

Signed on 18/01/of 2017

Represented by

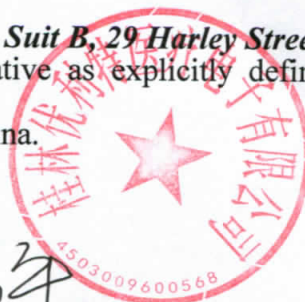
Place : Guilin, Guangxi, China.

Signature

Name of authorized signatory: Shi Ping

Position held in the company: General Manager

Seal/Stamp:



Product/s:

Urine Analyzer

Automatic Urine Analyzer

Detergent for Automatic Urine Analyzer

Auto Urine Sediment Analyzer

Detergent A

Detergent B

Detergent C

Calibrator Solution For Urine Analyzer

Quality Control Liquid For Urine Analyzer

Urine Reagent Strips

Urinalysis Control

Automated Hematology Analyzer

Control Material for Hematology Analyzer

Probe Cleaner

Diluent

Lytic Reagent

Detergent

5-Part-Diff Auto Hematology Analyzer

Lyse

Diluent

Sheath

Detergent

Automatic Chemistry Analyzer

Chemistry Analyzer

Microplate Reader

Microplate washer

Coagulation Analyzer

Electrolyte Analyzer

Electrolyte Analyzer Reagent

Hemoglobin Meter

Model:

URIT-50, URIT-180, URIT-500B, URIT-500C, URIT-30, URIT-330, URIT-31, URIT-560, URIT-30Vet, URIT-50Vet, URIT-31Vet

URIT-1500, URIT-1600

URIT D 12, D21, D21N

URIT-1200, URIT-1280, URIT-1000Plus

URIT D 11

URIT D 13

URIT D 14

URIT YC2ST

URIT YQ3STC

URIT 11F, 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 8A, URIT 10A, URIT 11A,

URIT 12F, URIT 14G, URIT 14F, URIT 11Vet

UQ-14, UQ-13, UQ-10, UQ-11

URIT-3000, URIT-3010, URIT-3000 Plus, URIT-

2900 Plus, URIT-3020, URIT-3200, URIT-

3060, URIT-3300, URIT-2900Vet Plus / 3000Vet

Plus

URIT QC 11

URIT D 43

URIT D 31

URIT L 21

URIT D 41

URIT-5500, URIT-5200, URIT-5250, URIT-

5260, URIT-5261, URIT-5160, URIT-5380, URIT-

5160Vet, URIT-5250Vet

URIT 5L 11

URIT 5D 11

URIT 5S 11

URIT D 46

URIT-8030, URIT-8060, URIT-8280, URIT-8260,

URIT-8236, URIT-8021A, URIT-8131, URIT-

8121A, URIT-8031, URIT-8210, URIT-8021A Vet

URIT-800, URIT-810, URIT-880,

URIT-800Vet, URIT-880Vet

URIT-660

URIT-670

URIT-610, URIT-600

URIT-910A, URIT-910C

URIT G-2, URIT G-1, URIT D, URIT E, URIT

F, URIT H, URIT A, URIT B, URIT C

URIT-12

Hemoglobin Test Strips	H12
Hemoglobin Control Solution	HQ-A
Albumin Reagent Kit (Bromcresol Green Method)	ALB
Alkanline Phosphatase Reagent Kit (Kinetic Method)	ALP
Alanine Aminotransferase Reagent Kit	
Amylase Reagent Kit	ALT
Aspartate Aminotransferase Reagent Kit	AMY
Calcium Reagent Kit	AST
Cholinesterase Reagent Kit	CA
Creatine Kinase Reagent Kit	CHE
Creatinine Reagent Kit (Picrate Acid Method)	CK
Direct Bilirubin Reagent Kit	CR
(Diazo Salt Method)	DB
Iron Reagent Kit	Fe
γ -Glutamyltransferase Reagent Kit	GGT
(Szasz Method)	
Glucose Reagent Kit	GLU-HK
(Hexokinase)	
Glucose Reagent Kit	GLU-OX
(Glucose oxidase)	
High-density Lipoprotein Reagent Kit	HDL-C
(Direct HDL Method)	
Lactate Dehydrogenase Reagent Kit	LDH
Low-density Lipoprotein Reagent Kit	LDL-C
(Direct LDL Method)	
Magnesium Reagent Kit	Mg
(Calmagite Method)	
Inorganic Phosphorus Reagent Kit	P
Total Bilirubin Reagent Kit(Diazo Salt Method)	TB-VA
Total Bile Acid Reagent Kit (Enzymatic Cycling Method)	TBA
Triglycerides Reagent Kit (GK,GPO Trinder Method)	TG
Total Protein Reagent Kit (Biuret Method)	TP
Uric Acid Reagent Kit	UA
Urea /BUN Reagent Kit	Urea
α -Hydroxybutyrate Dehydrogenase Reagent Kit	α -HBDH
Cholesterol Reagent Kit (Enzymagic Method)	CHOL
Reticulocyte Stain for hematology analyzer	URIT R11
Calibrator for Urine Sediment Analyzer	URIT CA21
Control Material for Urine Sediment Analyzer	URIT QC22
Maintenance agent for Urine Analyzer	URIT D 22
Control Material for Hematology Analyzer	URIT QC 11
Alkaline Detergent for Chemistry Analyzer	URIT DC1
Diluent	URIT AD 11
Lytic Reagent	URIT AL 11

