

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 61010-2-101:2002,

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 14971:2007, EN 61326-2-6:2013, EN 61000-3-2:2014, EN 61000-3-3:2013, EN 61010-1:2010, EN 61326-1:2013, EN 61010-2-101: 2017

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 19/11/of 2018

Place : Guilin, Guangxi, China.

Represented by

Signature 石平

Name of authorized signatory: Shi Ping

Position held in the company: General Manager

Seal/Stamp:



<i>Product/s:</i> Urine Analyzer	Model: URIT-50, URIT-180, URIT-500B, URIT-500C, URIT-30, URIT-330, URIT-31, URIT-560, URIT-30Vet, URIT-50Vet, URIT-31Vet
Automatic Urine Analyzer	URIT-1500, URIT-1600, UC-1800
Detergent for Automatic Urine Analyzer	URIT D 12, URIT D 21, URIT D 21N, URIT D 22
Auto Urine Sediment Analyzer	URIT-1200, URIT-1280, URIT-1000Plus, UD-1320
Detergent A	URIT D 11
Detergent B	URIT D 13
Detergent C	URIT D 14
Calibrator Solution For Urine Analyzer	URIT YC2ST
Quality Control Solution For Urine Analyzer	URIT YQ3STC
Urine Reagent Strips	URIT 11F, URIT 1V <sup>K</sup> , URIT 1V <sup>P</sup> , URIT 1V <sup>G</sup> , URIT 2V <sup>GK</sup> , URIT 2V <sup>PG</sup> , URIT 3V <sup>PGp</sup> , URIT 4V <sup>PGpSP</sup> , 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
Urinalysis Control	UQ-14, UQ-13, UQ-10, UQ-11
Automated Hematology Analyzer	URIT-3000, URIT-3010, URIT-3000 Plus, URIT-2900 Plus, URIT-3020, URIT-3200, URIT-3060, URIT-3300, URIT-2900Vet Plus / 3000Vet Plus
Probe Cleaner	URIT D 43
Diluent	URIT D 31
Lytic Reagent	URIT L 21
Detergent	URIT D 41
5-Part-Diff Auto Hematology Analyzer	URIT-5500, URIT-5200, URIT-5250, URIT-5260, URIT-5261, URIT-5160, URIT-5380, URIT-5160Vet, URIT-5250Vet
Lyse	URIT 5L 11
Diluent	URIT 5D 11
Sheath	URIT 5S 11
Detergent	URIT D 46
Automatic Chemistry Analyzer	URIT-8030, URIT-8060, URIT-8280, URIT-8260, URIT-8236, URIT-8021A, URIT-8131, URIT-8121A, URIT-8031, URIT-8210, URIT-8021AVet, URIT-8460, URIT-8400
Chemistry Analyzer	URIT-800, URIT-810, URIT-880, URIT-800Vet, URIT-880Vet
Microplate Reader	URIT-660
Microplate washer	URIT-670
Coagulation Analyzer	URIT-610, URIT-600
Electrolyte Analyzer	URIT-910A, URIT-910C
Electrolyte Analyzer Reagent	URIT G-2, URIT G-1, URIT D, URIT E, URIT F, URIT H, URIT A, URIT B, URIT C
Hemoglobin Meter	URIT-12
Hemoglobin Test Strip	H12
Hemoglobin Control Solution	HQ-A



Albumin Reagent Kit (Bromcresol Green Method)	ALB
Alkanline Phosphatase Reagent Kit (Kinetic Method)	ALP
Alanine Aminotransferase Reagent Kit	ALT
Amylase Reagent Kit	$\alpha$ -AMY
Aspartate Aminotransferase Reagent Kit	AST
Calcium Reagent Kit	Ca
Cholinesterase Reagent Kit	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	Fe
$\gamma$ -Glutamyltransferase Reagent Kit (Szasz Method)	GGT
Glucose Reagent Kit (Hexokinase)	GLU-HK
Glucose Reagent Kit (Glucose oxidase)	GLU-OX
High-density Lipoprotein Reagent Kit (Direct HDL Method)	HDL-C
Lactate Dehydrogenase Reagent Kit	LDH
Low-density Lipoprotein Reagent Kit (Direct LDL Method)	LDL-C
Magnesium Reagent Kit (Calmagite Method)	Mg
Inorganic Phosphorus Reagent Kit	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 (GK,GPO Trinder Method)	TG
Total Protein Reagent Kit (Biuret Method)	TP
Uric Acid Reagent Kit	UA
Urea /BUN Reagent Kit	Urea
$\alpha$ -Hydroxybutyrate Dehydrogenase Reagent Kit	$\alpha$ -HBDH
Cholesterol Reagent Kit (Enzymagic Method)	CHOL
Staining solution 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



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

