

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
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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 375:2001, EN 591:2001, EN 980:2008, EN 13612:2002+AC: 2002, EN 13640:2002,
EN ISO 13485:2003+AC: 2009, EN ISO 14971:2009

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

Place : Guilin, Guangxi, China.

Represented by

Signature

Name of authorized signatory: Li Youxing

Position held in the company: General Manager

Seal/Stamp:



Product/s: Urine Analyzer	Model: URIT-50, URIT-180, URIT-500B, URIT-500C, URIT-30, URIT-330, URIT-31, URIT-560 URIT-1500, URIT-1600 URIT D 12, URIT D 21, URIT D 21N URIT-1200, URIT-1280 URIT D 11 URIT D 13 URIT D 14 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 UQ-14, DQ-14, UQ-10, UQ-11, UQ-13 URIT-3000, URIT-3010, URIT-3000 Plus, URIT-2900 Plus, URIT-3020, URIT-3200, URIT-3060, URIT-3300, URIT D 43 URIT D 31 URIT L 21 URIT D 41 URIT-5500, URIT-5200, URIT-5250, URIT-5260, URIT-5261 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-800, URIT-810, URIT-880 URIT-660 URIT-670 URIT-610, URIT-600 URIT-910A, URIT-910C URIT A, URIT B, URIT C, URIT D, URIT E, URIT F, URIT G-1 URIT G-2, URIT-12 H12 HQ-A ALB ALP ALT AMY AST CA CHE CK CR DB Fe
Automatic Urine Analyzer	
Detergent for Automatic Urine Analyzer	
Auto Urine Sediment Analyzer	
Detergent A	
Detergent B	
Detergent C	
Urine Reagent Strips	
Urinalysis Control	
Automated 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	
Hemoglobin Test Strips	
Hemoglobin Control Solution	
Albumin Reagent Kit (Bromcresol Green Method)	
Alkanline Phosphatase Reagent Kit (Kinetic Method)	
Alanine Aminotransferase Reagent Kit	
Amylase Reagent Kit	
Aspartate Aminotransferase Reagent Kit	
Calcium Reagent Kit	
Cholinesterase Reagent Kit	
Creatine Kinase Reagent Kit	
Creatinine Reagent Kit (Picrate Acid Method)	
Direct Bilirubin Reagent Kit (Diazo Salt Method)	
Iron Reagent Kit	



γ -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(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
α -Hydroxybutyrate Dehydrogenase Reagent Kit	α -HBDH
Cholesterol Reagent Kit (Enzymagic Method)	CHOL
Urinalysis Calibrator	Cal-14
Alkaline Detergent for Chemistry Analyzer	U866A2010
Staining Solution for Hematology Analyzer	URIT R 11
Calibrator for Urine Sediment Analyzer	URIT CA21
Control Material for Urine Sediment Analyzer	URIT QC22
Maintenance agent for Urine Analyzer	URIT D22
Control Material for Hematology Analyzer	URIT QC 11
Auto Urine Sediment analyzer	URIT-1000Plus

