

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 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

Place: Guilin, Guangxi, China.

Represented by

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

