

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

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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

Automatic Urine Analyzer
Detergent for Automatic Urine Analyzer
Auto Urine Sediment Analyzer
Detergent A
Detergent B
Detergent C

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 (Bromocresol 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)

Model:

URIT-50, URIT-180, URIT-500B, URIT-500C,

URIT-1500, URIT-1600
URIT D 12, URIT D 21, RIT D 21 N
URIT-1200, URIT-1280
URIT D 11
URIT D 13
URIT D 14

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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 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-800, URIT-810, URIT-880

URIT-660
URIT-670
URIT-610,
RII-910A, URIT-910C
URIT A, RI I B, URIT C, URIT D, URIT E, URIT F,
URIT G, IURIT G-2.

URIT-12
H12
HQ-A

ALB

ALP
ALT
AMY
AST
CA
CHE
CK
CR



