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
ADD:No.D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P.R.China
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Digitally signed by Varman Irina
Date: 2024.12.10 14:58:03 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

CE

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),16 castle St ,Dover,CT16 1PW,UK and 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 30/12/of 2019 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-30, 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 8A, URIT 10A, URIT 11A, 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-8060, URIT-8280, URIT-8260, URIT-8021A , URIT-8031 ,URIT-8210, URIT-8021AVet,URIT-8460,URIT-8400
Chemistry Analyzer	URIT-800, URIT-810, URIT-880
Albumin Reagent Kit (Bromcresol Green Method)	ALB
Alkanline Phosphatase Reagent Kit (Kinetic Method)	ALP
Alanine Aminotransferase Reagent Kit	ALT
Amylase Reagent Kit	α-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
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(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（Uricase - Peroxidase Method）	UA
Urea /BUN Reagent Kit	Urea
α-Hydroxybutyrate Dehydrogenase Reagent Kit	α-HBDH
Cholesterol Reagent Kit (Enzymagic Method)	CHOL
Alkaline Detergent for Chemistry Analyzer	URIT DC1
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

Product/s:	Model:
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
Liporotein (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
Electrolyte Analyzer	URIT-910A, URIT-910C
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
Hemoglobin Test Strips	H12
Hemoglobin Control Solution	HQ-A

URIT 优利特

CE Technical Document

Declaration of Conformity

(Diluent)

(Model:URIT D31)

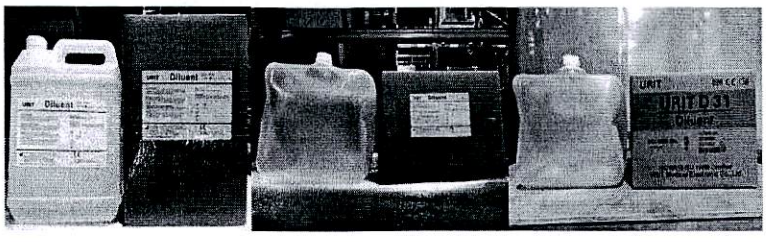
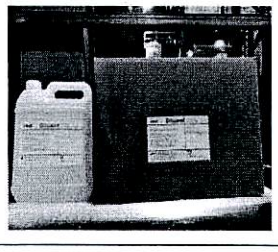
Document No: IVDR-URIT D31-CE09

Version/Revision No: 1.0

Department Distributed: Department II

Prepared by:	Verified by:	Approved by:
Xiong Ling	Huangqinbin	Su Qingwa
Technical Engineer	Technical Manager	PRRC

Declaration of Conformity

Manufacturer:	URIT Medical Electronic Co., Ltd. Address: No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P. R. China
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	Diluent
Model:	URIT D31
GMDN Code:	35781
EMDN Code:	W0103010105
SRN:	CN-MF-000011840
Basic UDI-DI:	69357404IBHS000005B9
Device Photograph:	 
Intended Use:	Diluent is appropriate to series of URIT automated hematology analyzers. With the function of measuring the blood cell content, it has an important effect to clinical diagnosis.
Risk Class:	Class A
Classification Rule:	Rule 5 (a) of Annex VIII of the Regulation (EU) 2017/746
Conformity Assessment Route	Article 48 section 10 of the Regulation (EU) 2017/746
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/746 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.	
Applied Standards:	EN ISO 13485:2016/AC:2018 EN ISO 14971:2019 EN ISO 15223-1:2021 EN ISO 18113-2: 2011 EN ISO 18113-1:2011

	EN ISO 23640: 2015 EN 13612: 2002		
Notified Body:	NA		
Identification Number:	NA		
(EC) Certificate(s):	NA	Valid until	NA
Start of CE-marking:	2022-3-20		
Place, Date of Issue:	Guilin, 2022-3-20		
Signature:	Name: Shiping Function: CEO		

URIT 优利特

CE Technical Document

Declaration of Conformity

(Lytic Reagent)

(Model:URIT L21)

Document No: IVDR-URIT L21-CE09

Version/Revision No: 1.0

Department Distributed: Department II

Prepared by:	Verified by:	Approved by:
Xiong Ling	Huangqinbin	Zhou Yong Yang
Technical Engineer	Technical Manager	PRRC

Declaration of Conformity

Manufacturer:	URIT Medical Electronic Co., Ltd. Address: No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P. R. China
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	Lytic Reagent
Model:	URIT L21
GMDN Code:	61165
EMDN Code:	W0103010105
SRN:	CN-MF-000011840
Basic UDI-DI:	69357404IBHS000003B5
Device Photograph:	
Intended Use:	Lytic Reagent is appropriate to series of URIT automated hematology analyzers. With the function of measuring the blood cell content, it has an important effect to clinical diagnosis.
Risk Class:	Class A
Classification Rule:	Rule 5 (a) of Annex VIII of the Regulation (EU) 2017/746
Conformity Assessment Route	Article 48 section 10 of the Regulation (EU) 2017/746
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/746 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for	

the DoC.			
Applied Standards:		EN ISO 13485:2016/AC:2018 EN ISO 14971:2019 EN ISO 15223-1:2021 EN ISO 18113-2: 2011 EN ISO 18113-1:2011 EN ISO 23640: 2015 EN 13612: 2002	
Notified Body:		NA	
Identification Number:		NA	
(EC) Certificate(s):	NA	Valid until	NA
Start of CE-marking:		2022-3-20	
Place, Date of Issue:		Guilin, 2022-3-20	
Signature:		Name: Shiping Function: CEO	

URIT 优利特

CE Technical Document

Declaration of Conformity

(Probe Cleaner)

(Model:URIT D43)

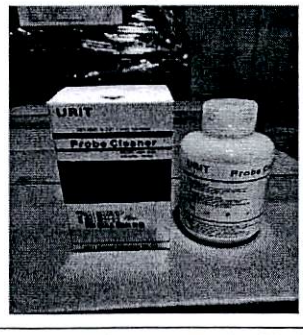
Document No: IVDR-URIT D43-CE09

Version/Revision No: 1.0

Department Distributed: Department II

Prepared by:	Verified by:	Approved by:
Xiong Ling	Huang Qinbin	Zhou Yong Yang
Technical Engineer	Technical Manager	PRRC

1. Declaration of Conformity

Manufacturer:	URIT Medical Electronic Co., Ltd. Address: No. D-07 Information Industry District, High-Tech Zone, Guilin, Guangxi 541004, P. R. China
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	Probe Cleaner
Model:	URIT D43
GMDN Code:	63377
EMDN Code:	W0103010105
SRN:	CN-MF-000011840
Basic UDI-DI:	69357404IBHS000002B3
Device Photograph:	
Intended Use:	Probe Cleaner used with blood cell analysis, to clean the instrument's probe or pipe. And it also can be used for daily maintenance.
Risk Class:	Class A
Classification Rule:	Rule 5 (a) of Annex VIII of the Regulation (EU) 2017/746
Conformity Assessment Route	Article 48 section 10 of the Regulation (EU) 2017/746
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/746 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.	
Applied Standards:	EN ISO 13485:2016/AC:2018 EN ISO 14971:2019 EN ISO 15223-1:2021 EN ISO 18113-2: 2011 EN ISO 18113-1:2011 EN ISO 23640: 2015

		EN 13612: 2002	
Notified Body:		NA	
Identification Number:		NA	
(EC) Certificate(s):	NA	Valid until	NA
Start of CE-marking:		2022-3-20	
Place, Date of Issue:		Guilin, 2022-3-20	
Signature:		Name: Shiping Function: CEO	