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TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

To whom it may concern

Munich, 2024-12-12  
Order No.: 713353134

**Confirmation concerning EU Quality Management System Certificate V12 074544 0021 Rev. 00**

We confirm that the following certificate:

**V12 074544 0021 Rev. 00** (valid until 2029-06-03)

issued to the legal medical device manufacturer:

**URIT Medical Electronic Co., Ltd.**  
**No. D-07**  
**Information Industry District**  
**High-tech Zone**  
**541004 Guilin, Guangxi**  
**PEOPLE'S REPUBLIC OF CHINA**

covers the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices with the scope:

**Classification: B**  
**Device Group: W0101 - CLINICAL CHEMISTRY**  
**Intended Purpose: IVR 0608 - Devices intended to be used for screening,determination or monitoring of physiological markers**

**Classification: B**  
**Device Group: W0202 - HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS**  
**Intended Purpose: IVR 0608 - Devices intended to be used for screening,determination or monitoring of physiological markers**

and the following devices:

Device Name	Basic UDI-DI	Ref No.
Urinalysis Control (Model:UQ-14, UQ-13, UQ-11, UQ-10)	69357404IUCS000002MR	USUC00001073,USUC00000974, USUC00001074,USUC00001075, USUC00001076,USUC00001077, USUC00001078,USUC00001079,

**Registered Office: Munich**  
Trade Register Munich HRB 85742  
UniCredit Bank GmbH · BIC HYVEDEMMXXX  
IBAN DE13 7002 0270 0048 8522 11  
VAT ID No. DE129484267  
Information pursuant to § 2 [1] DL-InfoV  
(Germany) at tuvsud.com/imprint

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Walter Reithmaier (CEO)  
Patrick van Welij

**TÜV SÜD Product Service GmbH**  
Ridlerstr. 65  
80339 Munich  
Germany

**tuvsud.com/ps**  
Hotline: +49 89 50084-747





Urine Reagent Strips (Model:URIT 11F, URIT 12F)	69357404IUCS000009N7	USUC00001020,USUC00001021
Urine Reagent Strips (Model:URIT 11FA, URIT 12FA, URIT 14FA, LabUSTicks 11F, LabUSTicks 12F, LabUSTicks 14F)	69357404IUCS000010MQ	USUC00001022,USUC00001023, USUC00001024,USUC00001059, USUC00001060,USUC00001061
Urine Reagent Strips (Model:UC 14GA, UC 13GA, UC 12GA, UC 11GA, UC 10GA, UC 10ACR)	69357404IUCS000011MS	USUC00001031,USUC00001032, USUC00001033,USUC00001034, USUC00001035,USUC00001036
Urine Reagent Strips (Model:URIT 10G, URIT 11G, URIT 14G, LabUSTicks 10G, LabUSTicks 11G, LabUSTicks 14G)	69357404IUCS000012MU	USUC00001025,USUC00001026, USUC00001027,USUC00001028, USUC00001029,USUC00001030
Urine Reagent Strips (Model: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 12V)	69357404IUCS000007N3	USUC00001057,USUC00001058, USUC00001055,USUC00001056, USUC00001053,USUC00001054, USUC00001107,USUC00001108, USUC00001051,USUC00001052, USUC00001049,USUC00001050, USUC00001047,USUC00001048, USUC00001045,USUC00001046, USUC00001043,USUC00001044, USUC00001041,USUC00001042, USUC00001039,USUC00001040, USUC00001037,USUC00001038
Urine Reagent Strips (Model:LabUSTicks 10A)	69357404IUCS000013MW	USUC00001062
Urine Reagent Strips (Model:HC-ACR, HC- 2U, HC-2D, HC-4U, HC-4K, HC-4D, HC-8T, HC-10T, HC-12TA, HC-14ACR)	69357404IUCS000014MY	USUC00001063,USUC00001064, USUC00001065,USUC00001066, USUC00001067,USUC00001068, USUC00001069,USUC00001070, USUC00001071,USUC00001072
Quality Control Solution for Urine Analyzer (Model:URIT YQ 3 <sup>STC</sup> , UNAMAX SG Control, UNAMAX COLOR Control, UNAMAX TURBIDITY Control)	69357404IUCS000005MX	USUC00001102,USUC00001101, USUC00001100,USUC00001099, USUC00001084,USUC00001085, USUC00001086,USUC00001087, USUC00001105,USUC00001104, USUC00001103
Calibrator Solution for Urine Analyzer (Model:URIT YC 2 <sup>ST</sup> , UNAMAX SG Calibra- tor, UNAMAX TURBIDITY Calibrator)	69357404IUCS000006MZ	USUC00001088,USUC00001088, USUC00001089,USUC00001090, USUC00001091,USUC00001092, USUC00001093,USUC00001094, USUC00001095,USUC00001096, USUC00001106,USUC00001097, USUC00001098
Quality Control Solution for Urine Analyzer (Model:UQC-4SG)	69357404IUCS000008N5	USUD00000285,USUD00000286
Control Material for Urine Sediment Analyzer (Model:URIT QC 22)	69357404IUSS000011XA	USUD00000238,USUD00000044, USUD00000045,USUD00000046, USUD00000239,USUD00000240, USUD00000047,USUD00000241, USUD00000242,USUD00000062, USUD00000063,USUD00000064, USUS00000116,USUS00000117, USUD00000065,USUD00000243,



		USUD00000244,USUD00000055, USUD00000056,USUD00000057, USUD00000245,USUD00000246, USUD00000058,USUD00000247, USUD00000248,USUD00000249, USUD00000250,USUD00000251, USUD00000252,USUD00000253, USUD00000254,USUD00000255, USUD00000256,U6030040M, U6030040N,U6030040P, USUD00000257,USUD00000258, U6070040M,USUD00000259, USUD00000260,USUD00000261, USUD00000262,USUD00000263, USUD00000264,USUD00000265, USUD00000266,USUD00000267, USUD00000268,USUD00000269, USUD00000270,USUD00000271, USUD00000272,USUD00000273, USUD00000274,USUD00000275, USUD00000276,USUD00000277, USUD00000278,USUD00000279, USUD00000280,USUD00000281, USUD00000282,USUD00000283
Calibrator for Urine Sediment Analyzer (Model:URIT CA 21)	69357404IUSS000010X8	USUD00000048,USUD00000284, U6050050M
Control Material for Urinalysis System (Model:URIT QC 33)	69357404IUSS000009XP	USUS00000123,USUS00000124, USUS00000074,USUS00000075, USUS00000125,USUS00000126, USUS00000127,USUS00000081, USUS00000080
Automated Hematology Analyzer (Model:URIT-3000Plus, URIT-3020)	69357404IBH000007KU	U2003000PM,UYBH00000470, UYBH00000468,UYBH00000509, UYBH00000493,UYBH00000543, UYBH00000489,UYBH00000490, UYBH00000492,UYBH00000491, UYBH00000469,U2003020M, UYBH00000472,UYBH00000471
5-Part-Diff Auto Hematology Analyzer (Model:URIT-5160, BH-5100, BH-5390)	69357404IBH000002KJ	U2005160M,UYBH00000482, UYBH00000211,UYBH00000614, UYBH00000207,UYBH00000737
5-Part-Diff Auto Hematology Analyzer (Model:BH-5380CRP, BH-5160CRP, BH-5160CS)	69357404IBH000004KN	UYBH00000247,UYBH00000253, UYBH00000251
5-Part-Diff Auto Hematology Analyzer (Model:BH-6100, BH-6180, BH-6500, BH-6580, BH-6600, BH-6680)	69357404IBH000006KS	UYBH00000870,UYBH00000639, UYBH00000871,UYBH00000642, UYBH00000872,UYBH00000643
Direct Bilirubin Reagent Kit (Vanadate Method)	69357404ICAS0000027M	U81185040M,U81189060M, U81122060M,U81120060M, U81181040M,U81190060M, U81121060M,U81182040M, U81182020M,U81185020M, U81189020M



Albumin Reagent Kit (Bromocresol Green Method)	69357404ICAS0000037P	U80481045M,U80489060M,U80420060M,U80411075M,U80481050M,U80489050M,U80421050M,U80482045M,U80411045M,U80489045M,U80481020M,U80485020M,U80489020M
Total Bilirubin Reagent Kit (Vanadate Method)	69357404ICAS0000067V	U81085040M,U81089060M,U81022060M,U81020060M,U81081040M,U81090060M,U81021060M,U81082040M,U81082020M,U81085020M,U81089020M
Total Protein Reagent Kit (Biuret Method)	69357404ICAS0000087Z	U80581045M,U80589060M,U80520060M,U80511075M,U80581050M,U80589050M,U80521050M,U80582045M,U80511045M,U80589045M,U80581020M,U80585020M,U80589020M
Low-density Lipoprotein Cholesterol Reagent Kit (Direct Method-Surfactant Removal Method)	69357404ICAS00000983	U83085045M,U83011060M,U83089060M,U83020060M,U83082045M,U83089045M,U83011030M,U83082030M,U83089030M,U83082015M,U83085015M,U83089015M
High-density Lipoprotein Cholesterol Reagent Kit (Direct Method-Selected Suppression Method)	69357404ICAS0000117N	U82985045M,U82911060M,U82989060M,U82920060M,U82982045M,U82989045M,U82911030M,U82982030M,U82989030M,U82982015M,U82985015M,U82989015M
Total Bile Acid Reagent Kit (Enzymatic Cycling Method)	69357404ICAS0000127Q	U80985045M,U80989060M,U80922060M,U80920060M,U80982045M,U80989045M,U80911030M,U80982030M,U80989030M,U80982015M,U80985015M,U80989015M
Alanine Aminotransferase Reagent Kit (Alanine Substrate Method)	69357404ICAS0000137S	U80785040M,U80720040M,U80789040M,U80720060M,U80721060M,U80781040M,U80790040M,U80782020M,U80785020M,U80789020M
Urea /BUN Reagent Kit (Urease Continuous Monitoring Method)	69357404ICAS0000147U	U81812020M,U81882020M,U81885020M,U81889020M,U81885040M,U81889060M,U81822060M,U81820060M,U81881040M,U81821060M,U81890060M,U81882040M
Cholesterol Reagent Kit (Esterase-Peroxidase Method)	69357404ICAS0000157W	U82785040M,U82720040M,U82789040M,U82720060M,U82722060M,U82782040M,U82790040M,U82782020M,U82785020M,U82789020M



$\gamma$ -Glutamyltransferase Reagent Kit (GCANA Substrate Method)	69357404ICAS0000167Y	U80012020M,U80082020M,U80085020M,U80089020M,U80085040M,U80020060M,U80089060M,U80022060M,U80081040M,U80021060M,U80090060M,U80082040M
Aspartate Aminotransferase Reagent Kit (Aspartic Acid Substrate Method)	69357404ICAS00001782	U80885040M,U80820040M,U80889040M,U80820060M,U80821060M,U80881040M,U80890040M,U80882020M,U80885020M,U80889020M
Triglycerides Reagent Kit (Enzymatic Method)	69357404ICAS00001884	U82812020M,U82882020M,U82885020M,U82889020M,U82885040M,U82820060M,U82889060M,U82822060M,U82881040M,U82821060M,U82890060M,U82882040M
Alkaline Phosphatase Reagent Kit (NPP-Kinetic Substrate-AMP Buffer Method)	69357404ICAS00001986	U80612020M,U80682020M,U80685020M,U80689020M,U80689060M,U80622060M,U80620060M,U80685040M,U80681040M,U80621060M,U80690060M,U80682040M
Uric Acid Reagent Kit (Uricase-Peroxidase Method)	69357404ICAS0000207P	U81985040M,U81930050M,U81920060M,U81989060M,U81922060M,U81982020M,U81985020M,U81989020M,U81981040M,U81921060M,U81990060M,U81982040M
$\alpha$ -Amylase Reagent Kit (EPS Substrate Method)	69357404ICAS0000227T	U86020030M,U86085040M,U86089060M,U86020060M,U86011025M,U86082025M,U86085025M,U86089025M,U86082050M,U86090050M,U86085050M,U86089050M
Creatinine Reagent Kit (Creatine Oxidase Method)	69357404ICAS0000237V	U81711015M,U81780030M,U81785045M,U81789060M,U81722060M,U81720060M,U81782015M,U81785015M,U81789015M,U81782030M,U81789030M,U81781045M,U81789045M
Cholinesterase (CHE) Test Kit (Butyryl Thi-ocholine Substrate Method)	69357404ICAS00002683	U86711020M,U86782040M,U86720060M,U86789060M,U86722060M,U86782020M,U86785020M,U86789020M,U86781040M,U86721060M,U86790060M,U86785040M
Multiple biochemical calibrators	69357404ICAS00003482	U90211005M,U90211030M,U90211050M
Multiple compound quality control products for biochemical immunity	69357404ICAS00003686	U90311005M,U90311030M,U90312005M,U90312030M,U90311050M,U90312050M




Assay Kit for Electrolytes Analysers (Ion-selective Electrode Method) (Model: ISE A, ISE B, CAL04, CAL08)	69357404ICAS0000398C	USCE00000041,USCE00000042, USCE00000034,USCE00000043
ISE Quality Control Material	69357404ICAS0000407V	U0701001M,U0701006M, U0701005M,U0701002M, U0701003M,U0701004M
Urinalysis Control (Model: UNAMAX U11 Control, UNAMAX U14 Control)	69357404IUCS000015N2	USUC00001080,USUC00001081, USUC00001082,USUC00001083
Urine Reagent Strips (Model: URIT 14F)	69357404IUCS000001MP	USUC00000973
Automated Hematology Analyzer (Model: BH-70P, BH-40P)	69357404IBH000001KG	UYBH00000235,UYBH00000562, UYBH00000241

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

  
 Georg Bauer  
 TÜV SÜD PRODUCT SERVICE GMBH  
 PS-MHS-AU-9  
 Medical Health Services Foreign Affairs

