

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Changchun WanCheng Bio Electron Co.,Ltd.

ADDRESS: No. 2336, Tianwei Road, Beihu Science and Technology Development Zone, Changchun City

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: lead test swab

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notified of the manufacture's device and has allocated registration. The registration number is **RPS/3793/2022**



Issue date: 25/May/2022

Cert. No.: R20220575-13



FDA

Fiscal Year 2025

CERTIFICATION OF REGISTRATION

This certifies that:

Name: CHANGCHUN WANCHENG BIO-ELECTRON CO., LTD

Add: No. 2336, Tianwei Road, Beihu Science and Technology Development Zone,
Changchun, Jilin, 130000, CHINA

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

Registration/FEI Number: 3008987086

Owner/Operator Number: 10049606

Listing No	Code	Premarket Submission NO.	Device Name
D489531	JRS	510(k) exempt	purifier, water (absorption, deionization, membrane filter, reverse osmosis) - Fluoride, Chromium/Cr, Copper, Lead, Hg, Iron, Cyanuric acid, pH, Hardness, Total alkalinity, Carbonate root; JNW Chlorine Test Strips - 100 Pack; Total chlorine, Free chlorine, Bromine, Nitrate, Nitrite, hydrogen sulfide, manganese, sulfate, zinc, sodium chloride ^e
D462666	LNW	510(k) exempt	paper, obstetric ph - Vaginal PH Test Strip
D462668	DFQ NRF	510(k) exempt	sperm, antigen, antiserum, control - Exploro Highly Male Fertility/Sperm Concentration Test; Fericare Male Fertility Test; Male Sperm Count Test; Palinoia ProGenix male fertility test; TREA Male Fertility Test

FDA

D462664	NGE	510(k) exempt	test, luteinizing hormone (lh), over the counter - Ovulation Urine Test Strip
D318333	KSL	510(k) exempt	solution, copper sulfate for specific gravity determinations - specific gravity
D544080	NGA	510(k) exempt	test, follicle stimulating hormone (fsh), over the counter - One step FSH rapid test
D245094	JJB	510(k) exempt	azo-dyes, colorimetric, bilirubin & its conjugates (urinary, non-quant.) - Urinary Test Non-Quant
D245098	KQO	510(k) exempt	automated urinalysis system - Automated Urinalysis system; Semi-Automatic Urine Analyzer
D245092	JIN	510(k) exempt	nitroprusside, ketones (urinary, non-quant.) - Ketone Test Strip; Urinary Test Non-Quant.
D462697	GOO	510(k) exempt	antisera, fluorescent, all globulins, salmonella spp. - Salmonella (fluorescence analysis); Salmonella test (colloidal gold); Salmonella test (fluorescence analysis)
D309523	IGD	510(k) exempt	solution, formol calcium - Calcium
D309522	JLA	510(k) exempt	conversion to creatinine, creatine - Creatinine
D245097	LJX	510(k) exempt	test, urine leukocyte - Urine Test; URS 3N teststrip.
D493561	JNQ	510(k) exempt	qualitative chemical reactions, urinary calculi (stone)

FDA

D510507	NRF	510(k) exempt	material, quality control, semen analysis - Male Sperm Count Test; Palinoia ProGenix male fertility test
D462696	GNA	510(k) exempt	antisera, all types, escherichia coli - Escherichia coli test (colloidal gold); Escherichia coli test (powder)
D245090	CDM	510(k) exempt	diazonium colorimetry, urobilinogen (urinary, non-quant.) - Urinary Test Non- Quant., Diazonium colorimetry; Urobilinogen
D245093	JIR	510(k) exempt	indicator method, protein or albumin (urinary, non-quant.) - Urinary Test Non- Quant., Protein; Urine Test Strip for Albumin-to-Creatinine Ratio
D245095	JMA	510(k) exempt	acid, ascorbic, 2,4- dinitrophenylhydrazine (spectrophotometric) - Acid Ascorbic; Acid Test.
D313367	LXG	510(k) exempt	equipment, laboratory, general purpose, labeled or promoted for a specific medical use - Alatoxin B1 Quantitative Test(Time-Resolved Fluoroimmunoassay); B1 Vomitoxin QuantitativeTest(Time-Res Olvedfluoroimmunoassay); JNW Drinking Water Test Strips - 17-in-1 100 Pack; JNW Water Hardness Test Strips - 100 Pack; JNW Water Hardness Test Strips - 150ct; Oil Test Strip; Water Test Strips, Reagent Strips For Water; Zearalenone Quantitative Test(Time- ResolvedfluoroimmunoasSay)

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D245096	JMT	510(k) exempt	diazo (colorimetric), nitrite (urinary, non-quant) - Nitric oxide test; Urinary Test Non-Quant; URS 3N teststrip.
D462694	KNK	510(k) exempt	acid, uric, uricase (colorimetric) - Uric Acid test
D245091	CEN	510(k) exempt	dye-indicator, ph (urinary, non-quantitative) - Body pH Levels Test Strips to Track and Monitor Your pH Balance Test Strips for Women; Gastric Aspirate ph test; JNW PH Test Strips - 0-14 PH 200 Pack; JNW PH Test Strips - 4.5-9 PH 200 Pack; JNW pH Test Strips 0-14; JNW pH Test Strips 4.5-9; pH 0-14; pH Paper Test Strips Kit for Results in Seconds with Litmus Paper, pH Scale 4.5-9; pH Testing Strips 120ct; Universal Ph Test Strip (4.5 - 9.0); Urinary Test Non-Quant., PH; URS 3N teststrip.
D462693	JXA	510(k) exempt	kit, screening, urine - aflatoxin (colloidal gold); Free Radical test; JNW Direct Lead Test Swabs - 10 pack; Lead test (colloidal gold); Lead Test Swab; Test For The Concentration of Ortho-phthalaldehyde test; Urine Megnesium test; Urine Salinity test; Urine Zinc Test; VC

FDA

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate - holder's device or establishment by the U.S Food and Drug Administration. ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Nov. 4, 2024

Date of expiration: Dec.31, 2025

SH OFFICE

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