

AUTHORIZATION LETTER

Wr. Neudorf, 20.08.2024

TO WHOM IT MAY CONCERN

We, **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**, headquarter in Austria, IZ-NÖ Süd, Hondastrasse Obj. M55, A-2351 Wr. Neudorf hereby declares that the below mentioned company is our **distributor** and is authorized to register, sell and distributor our products in the territory of Moldavia:

ECHIPAMED PLUS SRL
Valea Trandafirilor str., 24B, of.80,
MD-2001 Chisinau, Moldova

This certificate remains in force until 31.12.2025 or is terminated during that period on the expiry of not less than 30 days' notice in writing given by either party to the other.

Signed for and on behalf of
DIALAB GmbH


Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Murat ESTELIK
Managing Director

DIALAB Produktion und Vertrieb
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Produkten und Laborinstrumenten
Gesellschaft m.b.H.

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Managing Director | Geschäftsführer
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Reifen Regionalbank Moedling
BIC / SWIFT: RLNWAT3333
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DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 026709 0009 Rev. 01

Holder of Certificate: DIALAB Produktion und Vertrieb von
chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H.

IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Certification Mark:



Scope of Certificate: Design, development, production and distribution of
in-vitro diagnostic reagents and testkits in the areas of
immunological detection of infectious diseases,
immunochemistry/immunology/clinical chemistry
biomarkers (analytes: enzymes, substrates,
electrolytes reagents; controls/standards/calibrators),
urinalysis, haematology, haemostasis and
immunohaematology (blood grouping).
Distribution of in-vitro diagnostic instruments including
accessories for immunology, clinical chemistry,
haematology, haemostasis and urinalysis.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned
above has established and is maintaining a quality management system, which meets the
requirements of the listed standard(s). All applicable requirements of the testing and certification
regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 026709 0009 Rev. 01

Report No.: 713237224

Valid from: 2022-03-29

Valid until: 2025-03-28

Date, 2022-03-17

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q5 026709 0009 Rev. 01

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): DIALAB Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf,
AUSTRIA

See Scope of Certificate

Parameters: ./.



EC DECLARATION OF CONFORMITY
EG-KONFORMITÄTSERKLÄRUNG



Dialab Produktion und Vertrieb von
chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf

REF	Product Name / Produktname	Content / Inhalt
	See addendum to the declaration of Conformity	

We declare, on our own responsibility, that our above-mentioned product classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II

meets the applicable provisions of the EU Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on the Conformity Assessment Procedure according to Annex III of the aforesaid Directive.

Hiermit erklären wir, auf eigene Verantwortung, dass unser oben genanntes Produkt, gemäß der Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert als:

Andere als die in Anhang II genannten Produkte

die anwendbaren Vorschriften der EU-Richtlinie 98/79/EG über in-Vitro-Diagnostika und des Österreichischen Medizinproduktegesetzes erfüllt.

Diese Erklärung basiert auf dem Konformitätsbewertungsverfahren nach Anhang III der oben angeführten Richtlinie

Wiener Neudorf, 2023-10-04

Almira Dugic
Qualitätsmanagementbeauftragte
Quality Management Representative

Addendum to the Declaration of Conformity of Devices other than those covered by Annex II

DIAQUICK RAPID TESTS

Drugs of Abuse - Cassettes

REF	Product	Content
Z22101CE	DIAQUICK 6-MAM Cassette	30 Tests (30x REF Z22101B)
Z99004CE	DIAQUICK AMP Cassette	30 Tests (30x REF Z99004B)
Z99006CE	DIAQUICK BAR Cassette	30 Tests (30x REF Z99006B)
Z04560CE	DIAQUICK BUP Cassette	30 Tests (30x REF Z04560B)
Z99001CE	DIAQUICK BZO Cassette	30 Tests (30x REF Z99001B)
Z99003CE	DIAQUICK COC Cassette	30 Tests (30x REF Z99003B)
Z15102CE	DIAQUICK ETG Cassette	30 Tests (30x REF Z15102B)
Z09640CE	DIAQUICK FYL Cassette	10 Tests (10x REF Z09640B)
Z09641CE	DIAQUICK KET Cassette	10 Tests (10x REF Z09641B)
Z15106CE	DIAQUICK LSD Cassette	30 Tests (30x REF Z15106B)
Z04570CE	DIAQUICK MDMA Cassette	30 Tests (30x REF Z04570B)
Z99500CE	DIAQUICK MET Cassette	30 Tests (30x REF Z99500B)
Z99005CE	DIAQUICK MOP Cassette	30 Tests (30x REF Z99005B)
Z99550CE	DIAQUICK MTD Cassette	30 Tests (30x REF Z99550B)
Z05011CE	DIAQUICK OPI Cassette	30 Tests (30x REF Z05011B)
Z06007CE	DIAQUICK OXY Cassette	30 Tests (30x REF Z06007B)
Z13630CE	DIAQUICK Spice Cassette	30 Tests (30x REF Z13630B)
Z03040CE	DIAQUICK TCA Cassette	30 Tests (30x REF Z03040B)
Z99002CE	DIAQUICK THC Cassette	30 Tests (30x REF Z99002B)
Z10414CE	DIAQUICK TRA Cassette	30 Tests (30x REF Z10414B)

Drugs of Abuse - Dipsticks

REF	Product	Content
Z02504CE	DIAQUICK AMP Dipstick	50 Tests (50x REF Z02504B)
Z02506CE	DIAQUICK BAR Dipstick	50 Tests (50x REF Z02506B)
Z02501CE	DIAQUICK BZO Dipstick	50 Tests (50x REF Z02501B)
Z02510CE	DIAQUICK COC Dipstick	50 Tests (50x REF Z02510B)
Z05610CE	DIAQUICK MDMA Dipstick	50 Tests (50x REF Z05610B)
Z02500CE	DIAQUICK MET Dipstick	50 Tests (30x REF Z02500B)
Z02505CE	DIAQUICK MOP Dipstick	50 Tests (50x REF Z02505B)
Z02550CE	DIAQUICK MTD Dipstick	50 Tests (50x REF Z02550B)
Z02560CE	DIAQUICK PCP Dipstick	50 Tests (50x REF Z02560B)
Z02502CE	DIAQUICK THC Dipstick	50 Tests (50x REF Z02502B)

Drugs of Abuse - Saliva Tests

REF	Product	Content
Z06677CE	DIAQUICK Alcohol Saliva Strips	25 Tests (25x REF Z06677B)

Drugs of Abuse - Multi-Parameter Tests

REF	Product	Content
Z06576CE	DIAQUICK Multi-3 Drug Panel	30 Panels (30x REF Z06576B)
Z09577CE	DIAQUICK Multi-3/1 Drug Panel	30 Panels (30x REF Z09577B)
Z02575CE	DIAQUICK Multi-4 Drug Panel	30 Panels (30x REF Z02575B)
Z06502CE	DIAQUICK Multi-5/3 Drug Panel	30 Panels (30x REF Z06502B)
Z11504CE	DIAQUICK Multi-5/4 Drug Panel	30 Panels (30x REF Z11504B)
Z06506CE	DIAQUICK Multi-5/6 Drug Panel	30 Panels (30x REF Z06506B)
Z98907CE	DIAQUICK Multi-6 Drug Panel	30 Panels (30x REF Z98907B)
Z03220CE	DIAQUICK Multi-6/1 Drug Panel	30 Panels (30x REF Z03220B)

Z08940CE	DIAQUICK Multi-6/4 Drug Panel	30 Panels (30x REF Z08940B)
Z09970CE	DIAQUICK Multi-6/7 Drug Panel	30 Panels (30x REF Z09970B)
Z11911CE	DIAQUICK Multi-6/10 Drug Panel	30 Panels (30x REF Z11911B)
Z12730CE	DIAQUICK Multi-7 Drug Panel	30 Panels (30x REF Z12730B)
Z06230CE	DIAQUICK Multi-10 Drug Panel	30 Panels (30x REF Z04230B)
Z04231CE	DIAQUICK Multi-10 Drug Panel	10 Panels (10x REF Z04230B)
Z06235CE	DIAQUICK Multi-10/1 Drug Panel	30 Panels (30x REF Z05235B)
Z06236CE	DIAQUICK Multi-10/1 Drug Panel	10 Panels (10x REF Z05235B)
Z06103CE	DIAQUICK Multi-10/3 Drug Panel	30 Panels (30x REF Z06103B)
Z06104CE	DIAQUICK Multi-10/4 Drug Panel	30 Panels (30x REF Z06104B)
Z06106CE	DIAQUICK Multi-10/6 Drug Panel	30 Panels (30x REF Z06106B)
Z06107CE	DIAQUICK Multi-10/7 Drug Panel	30 Panels (30x REF Z06107B)
Z06667CE	DIAQUICK DOA Multi-6 Cup	1 Test

Cardiac Markers

REF	Product	Content
Z08234CE	DIAQUICK Cardiac Combo Cassette	20 Tests (20x REF Z08233B)
Z08233CE	DIAQUICK Cardiac Combo Cassette	5 Tests (5x REF Z08233B)
Z08120CE	DIAQUICK Troponin I Cassette	30 Tests (30x REF Z08120B)
Z08125CE	DIAQUICK Troponin I Cassette	5 Tests (5x REF Z08120B)
Z20300CE	DIAQUICK Troponin T Cassette	30 Tests (30x REF Z20300B) 3x 3mL Buffer
Z20301CE	DIAQUICK Troponin T Cassette	10 Tests (10x REF Z20300B) 1x 3mL Buffer

Tumor Markers

REF	Product	Content
Z06020CE	DIAQUICK AFP Cassette	30 Tests (30x REF Z03020B) 2x 3 mL Buffer
Z06030	DIAQUICK CEA Cassette	30 Tests (30x Z03030B) 2x 3 mL Buffer
Z01101CE	DIAQUICK FOB Cassette	25 Tests (25x Z01101B) 25 Collection Tubes with a 2mL Buffer
Z01102CE	DIAQUICK FOB Cassette	5 Tests (5x REF Z01101B) 5 Collection Tubes with a 2mL Buffer
J13101CE	DIAQUICK FOB-TRF Combi Cassette	20 Tests (20x J13101BN) 20 Collection Tubes with Buffer

Pregnancy / Fertility

REF	Product	Content
Z98404CE	DIAQUICK hCG Cassette	30 Tests (30x REF Z98404B)
J01402-1CE	DIAQUICK hCG Dipstick	50 Tests (50x REF J01402-1B)
J01402-2CE	DIAQUICK hCG Dipstick	50 Tests (50x REF J01402-2B)
Z01405CE	DIAQUICK hCG Combo Cassette	30 Tests (30x REF Z01405B)
Z03403-1CE	DIAQUICK hCG Combo Dipstick	50 Tests (50x REF Z03403-1B)
Z03403-2CE	DIAQUICK hCG Combo Dipstick	50 Tests (50x REF Z03403-2B)
Z98502CE	DIAQUICK LH Cassette	30 Tests (30x REF Z98502B)
Z06507CE	DIAQUICK LH Dipstick	50 Tests (50x REF Z06507B)

Others

REF	Product	Content
Z06021	DIAQUICK CRP Cassette	20 Tests 20 tests individually packed 20 disposable pipettes 20 extraction tubes with buffer

Z08070CE	DIAQUICK Microalbumin Dipstick	50 Tests 50 tests individually packed
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Infectious Diseases - ToRCH

REF	Product	Content
J15040CE	DIAQUICK HSV 1/2 IgM Cassette	25 Tests (25x REF J15040B) 1x 3 mL Buffer

Other Infectious Diseases

REF	Product	Content
Z09620CE	DIAQUICK Adenovirus Cassette	5 Tests (5x REF Z09620B) 5 Collection Tubes with Buffer
Z20401CE	DIAQUICK COVID-19 Ag Cassette	20 Tests (20x REF Z20401B) 2 Buffer
Z20999CE	DIAQUICK COVID-19 Ag Cassette	20 Tests (20x REF Z20601B) 20 Buffer
Z20601CE	DIAQUICK COVID-19 Ag Cassette	20 Tests (20x REF Z20601B) 20 Buffer
Z06240	DIAQUICK Dengue IgG/IgM Ab Cassette	30 Tests 30 tests individually packed 30 disposable capillary pipettes (10 µL) 1x 3 mL Buffer
Z17240CE	DIAQUICK Dengue NS1 Ag Cassette	30 Tests 30 tests individually packed 30 disposable pipettes
Z17241CE	DIAQUICK Dengue Combo Cassette	20 Tests 20 tests individually packed 20 disposable capillary pipettes (10 µL) for Dengue IgG/IgM 20 disposable pipettes for Dengue NS1
Z06229CE	DIAQUICK H.pylori Cassette	30 Tests (30x REF Z98229B) 1x 3 mL Buffer
Z08090CE	DIAQUICK H.pylori Stool Cassette	20 Tests (20x REF Z08090B) 20 Collection Tubes with Buffer
Z08091CE	DIAQUICK H.pylori Stool Cassette	5 Tests (5x REF Z08090B) 5 Collection Tubes with Buffer
Z09440CE	DIAQUICK Influenza Ag Dipstick	25 tests 25 tests individually packed 25x 0.3 mL buffer tubes 25 sterilized swabs, individually packed 3 control swabs (A+, B+, negative) 1 working rack
W06200	DIAQUICK Malaria P.f. Cassette	30 tests 30 tests individually packed 2 buffer tubes 30 disposable sample applicators (5µL) 30 disposable lancets 30 alcohol pads
Z11200CE	DIAQUICK Malaria P.f./Pan Cassette	25 tests 25 tests individually packed 1 buffer tube 25 disposable sample applicators (5µL) 30 disposable lancets 30 alcohol pads
Z06620CE	DIAQUICK Mononucleosis Cassette	30 Tests (30x REF Z05620B) 30 tests individually packed

Z09610CE	DIAQUICK Rotavirus Cassette	1x 5 mL Buffer 1x 1 mL negative control 1x 1 mL positive control 5 Tests (5x REF Z09610B) 5 Collection Tubes with Buffer
Z09600CE	DIAQUICK Rota/Adeno Combi Cassette	5 tests 25 tests individually packed 5x collection tubes with 1.5 mL buffer each
Z09601CE	DIAQUICK Rota/Adeno Combi Cassette	30 tests 30 tests individually packed 5x collection tubes with 1.5 mL buffer each
Z98223CE	DIAQUICK Strep. A Cassette	20 Tests (20x REF Z98223B) 20 cassettes individually packed 1x 10 mL Extraction Reagent A 1x 10 mL Extraction Reagent B 1x 1 mL positive control 1x 1 mL negative control 20 extraction tubes and caps 20 sterile swabs 1 work station
Z98230CE	DIAQUICK Strep.A Dipstick	20 Tests (20x REF Z98230B) 20 cassettes individually packed 1x 10 mL Extraction Reagent A 1x 10 mL Extraction Reagent B 1x 1 mL positive control 1x 1 mL negative control 20 extraction tubes 20 sterile swabs 1 work station
Z06903CE	DIAQUICK Syphilis Cassette	30 tests 30 tests individually packed 30 disposable pipettes 2 vials buffer
Z12903CE	DIAQUICK Syphilis Dipstick	25 tests 25 tests individually packed 25 test cards 2 vials buffer 1 vial buffer
Z11450	DIAQUICK S.typhi IgG/IgM Ab Cassette	25 tests 25 tests individually packed 25x 5 µL capillary pipettes 1x 5mL buffer
Z11451	DIAQUICK S.typhi/paratyphi Ag Cassette	25 Tests (25x REF Z11451B) 25 Collection Tubes with Buffer