

AUTHORIZATION LETTER

Wr. Neudorf, 07.01.2020

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 official **representative** 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 from 01.01.2020 until 31.12.2020 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 Produktion und Vertrieb von
chemisch-technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H**
Objekt M55
A-2351 Wr. Neudorf
AUSTRIA



Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
A-2351 Wr. Neudorf, IZ-NÖ Süd, Hondastrasse Obj. M55
Phone: +43 (0) 2236 660910-0 | Fax: +43 (0) 2236 660910-30
E-Mail: office@dialab.at | Web: www.dialab.at

Christina Schneider
Export Manager



Product Service

Certificate

No. Q5 026709 0009 Rev. 00

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

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

Certification Mark:



Scope of Certificate: **Design and development, production and distribution of reagents and reagent products for in-vitro diagnostics as well as distribution of instruments for in-vitro diagnostics including accessories**

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

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). See also notes overleaf.

Report No.: 713146001

Valid from: 2019-03-29
Valid until: 2022-03-28

Date, 2019-03-28

Stefan Preiß

EC DECLARATION OF CONFORMITY

We



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

declare, on our own responsibility, that our products specified in the enclosed
addendum "Devices other than those covered by Annex II (Rapid Tests),
Rev.12 (3 pages)", classified as follows according to the directive on in vitro
diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Rapid Tests)

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

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

This Declaration is valid until 2022-03-28.



DIALAB
Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
A - 2351 Wr. Neudorf, IZ NOE Sued, Objekt M55
Phone: ++43 (0)2236 660910-0 | Fax: ++43 (0)2236 660910-30
E-Mail: office@dialab.at | Website: www.dialab.at

Wr. Neudorf, 2019-04-02

DI Marlene Ramsey
Managing Director

Addendum to the Declaration of Conformity of Devices other than those covered by Annex II (Rapid Tests)



Cardiac Markers

	REF	Content
DIAQUICK Cardiac Combo Cassette	Z08234CE	- 20 Tests (20x REF Z08233B)
	Z08233CE	- 5 Tests (5x REF Z08233B)
DIAQUICK Troponin I Cassette	Z08120CE	- 30 Tests (30x REF Z08120B)
	Z08125CE	- 5 Tests (5x REF Z08120B)

Tumour Markers

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

Pregnancy / Fertility

	REF	Content
DIAQUICK hCG Cassette	Z98404CE	- 30 Tests (30x REF Z98404B)
DIAQUICK hCG Dipstick (5 mm)	J01402-1CE	- 50 Tests (50x REF J01402-1B)
DIAQUICK hCG Dipstick (3 mm)	J01402-2CE	- 50 Tests (50x REF J01402-2B)
DIAQUICK hCG Combo Cassette	Z01405CE	- 30 Tests (30x REF Z01405B)
DIAQUICK hCG Combo Dipstick (5 mm)	Z03403-1CE	- 50 Tests (50x REF Z03403-1B)
DIAQUICK hCG Combo Dipstick (3 mm)	Z03403-2CE	- 50 Tests (50x REF Z03403-2B)
DIAQUICK LH Cassette	Z98502CE	- 30 Tests (30x REF Z98502B)
DIAQUICK LH Dipstick	Z06507CE	- 50 Tests (50x REF Z06507B)

Others

	REF	Content
DIAQUICK CRP Cassette	Z06021	- 20 Tests (20x REF Z06021B)
		- 20 Extraction Tubes with Buffer
DIAQUICK Microalbumin Dipstick	Z08070CE	- 50 Tests (50x REF Z08070B)

Infectious Diseases - ToRCH

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

Other Infectious Diseases

	REF	Content
DIAQUICK Adenovirus Cassette	Z09620CE	- 5 Tests (5x REF Z09620B)
		- 5 Collection Tubes with Buffer
DIAQUICK Dengue IgG/IgM Ab Cassette	Z06240	- 30 Tests (30x REF Z06240B)
		- 1x 3 mL Buffer
DIAQUICK Dengue NS1 Ag Cassette	Z17240CE	- 30 Tests (30x REF Z17240B)
DIAQUICK Dengue Combo Cassette	Z17241CE	- 20 Tests (20x REF Z17241B)
		- 1x 3 mL Buffer
DIAQUICK H.pylori Cassette	Z06229CE	- 30 Tests (30x REF Z98229B)
		- 1x 3 mL Buffer
DIAQUICK H.pylori Stool Cassette	Z08090CE	- 20 Tests (20x REF Z08090B)
		- 20 Collection Tubes with Buffer
	Z08091CE	- 5 Tests (5x REF Z08090B)
		- 5 Collection Tubes with Buffer
DIAQUICK Influenza Ag Dipstick	Z09440CE	- 25 Tests (25x REF Z09440B)
		- 25 Collection Tubes with Buffer
		- 3 Control Swabs
DIAQUICK Malaria P.f. Cassette	W06200	- 30 Tests (30x REF W04200B)
		- 2x 3 mL Buffer