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AUTHORISATION LETTER

Wr. Neudorf, 06.02.2019

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 01.01.2019 until 31.12.2019 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

Christina Schneider
Export Manager

REPUBLICA MOLDOVA mun. CHIŞINĂU. SOCIETATEA CU RĂSPUNDERE LIMITATĂ «ECHIPAMED-PLUS» IDNO 1003600077677

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Deutsche
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TÜV SÜD
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.**
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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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

I. Preiß

Stefan Preiß

Date, 2019-03-28

"ECHIPAMED-PLUS" REPUBLICA MOLDOVA, mun. CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ IDNO 1003600077677

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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
A-2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed addendum
"Devices of List A, Annex II (mdc), Rev.06 (1 page)",
classified as follows according to the directive on in vitro diagnostic medical devices
98/79/EC:

Devices of List A, Annex II

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 IV, section 3 and 4 of the aforesaid Directive in cooperation with the notified body

mdc medical device certification GmbH, code no. 0483
Kriegerstraße 6 / 70191 Stuttgart / Germany

This Declaration is valid until 2021-04-22.

Wr. Neudorf, 2017-12-21

DI Marlene Ramsey
Managing Director

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Addendum to the Declaration of Conformity of Devices for List A, Annex II (mdc)

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ABO and Rhesus Typing	REF	CONT	LOT
Anti-A, monoclonal	B05405	10 mL	*600129-B2, 600129-B3, 600134-A4, 600135-A3, 600135-C2, 600136-H2, 600139-A4*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-B, monoclonal	B05406	10 mL	*610154-A2, 610156-B3, 610159-A4, 610159-C3, 610160-A2, 610161-G2, 610164-H3*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-AB, monoclonal	B05407	10 mL	*620116-B3, 620119-C2, 620121-C2, 620124-B3, 620125-F3*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-D (IgM/IgG), monoclonal	B05408	10 mL	*740156-B2, 740158-B3, 740162-A2, 740162-B4, 740162-D2, 740163-F3, 740163-H2*
CE-Certificate No.: D4000100004 and D4000100005			
Anti-D Negative Control	B09936	10 mL	*650293-B7*
CE-Certificate No.: D4000100004 and D4000100005			

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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.

Wr. Neudorf, 2019-04-02

DI Marlene Ramsey
Managing Director

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Addendum to the Declaration of Conformity of Devices other than those covered by Annex II (Rapid Tests)

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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

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

DIAQUICK Malaria P.f./Pan Cassette	Z11200CE	- 25 Tests (25x REF Z11200B) - 1x 3 mL Buffer
DIAQUICK Mononucleosis Cassette	Z06620CE	- 30 Tests (30x REF Z05620B) - 1x 5 mL Buffer - 1x 1 mL Positive Control - 1x 1 mL Negative Control
DIAQUICK Rotavirus Cassette	Z09610CE	- 5 Tests (5x REF Z09610B) - 5 Collection Tubes with Buffer
DIAQUICK Rota/Adeno Combi Cassette	Z09600CE	- 5 Tests (5x REF Z09600B) - 5 Collection Tubes with Buffer
	Z09601CE	- 30 Tests (30x REF Z09600B) - 30 Collection Tubes with Buffer
DIAQUICK Strep.A Cassette	Z98223CE	- 20 Tests (20x REF Z98223B) - 1x 10 mL Extraction Reagent A - 1x 10 mL Extraction Reagent B - 1x 1 mL Positive Control - 1x 1 mL Negative Control
DIAQUICK Strep.A Dipstick	Z98230CE	- 20 Tests (20x REF Z98230B) - 1x 10 mL Extraction Reagent A - 1x 10 mL Extraction Reagent B - 1x 1 mL Positive Control - 1x 1 mL Negative Control
DIAQUICK Syphilis Cassette	Z06903CE	- 30 Tests (30x REF Z03903B) - 2x 3 mL Buffer
DIAQUICK Syphilis Dipstick	Z12903CE	- 25 Tests (25x REF Z12903B) - 1x 3 mL Buffer
DIAQUICK S.typhi IgG/IgM Ab Cassette	Z11450	- 25 Tests (25x REF Z11450B) - 1x 6 mL Buffer
DIAQUICK S.typhi/paratyphi Ag Cassette	Z11451	- 25 Tests (25x REF Z11451B) - 25 Collection Tubes with Buffer

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DECLARATION OF CONFORMITY

We

Dialab Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m. b. H.
IZ-NÖ Süd, Hondastrasse, Objekt M55
2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed addendum "Devices other than those covered by Annex II (Clinical Chemistry)", Rev.18 (8 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 (Clinical Chemistry)

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

Wr. Neudorf, 2019-04-04

Marlene Ramsey
Managing Director

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
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Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)

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	REF	CONT
Potassium, *Enzymatic*	914105	5 x 100 ml
	914106	5 x 50 ml
	914107	5 x 25 ml
	910110	5 x 10 ml
	948911	1 x 50 ml
	9A0851	5 x 20 ml
	9T1051	5 x 20 ml
	9E1851	2 x 62,5 ml
Protein Total, *Biuret*	D03120B	1 x 1,25 ml
	D95680	5 x 100 ml
	D00685	5 x 50 ml
	D00686	5 x 25 ml
	D00687	5 x 10 ml
	D80911	10 x 50 ml
	D0437917	5 x 62,5 ml
	DK0738	5 x 50 ml
	DA0841	5 x 50 ml
	DT1041	4 x 62,5 ml
	DE1841	8 x 62,5 ml
Protein Total Mono, *Biuret*	D12681B	1 x 1 L
	D12680	5 x 100 ml
	D13685	5 x 50 ml
	D13686	5 x 25 ml
	D13687	5 x 10 ml
	D43911	10 x 50 ml
	D0448917	9 x 65 ml
	DA1353	5 x 50 ml
	DT1353	4 x 50 ml
	DK1346	5 x 50 ml
	DE1853	10 x 50 ml
Protein Total in Urine/CSF, *Pyrogallol red*	D03127B	1 x 1 L
	D03200	5 x 25 ml
	D79911	5 x 50 ml
	D0436917	9 x 65 ml
	DK0739	5 x 50 ml
	DA1042	5 x 20 ml
	DT1042	5 x 20 ml
	DE1842	5 x 20 ml
Triglycerides, *GPO-PAP*	D98386B	1 x 1 L
	D08388	4 x 250 ml
	D00389	5 x 100 ml
	D96388	5 x 50 ml
	D00390	5 x 25 ml
	D98390	5 x 10 ml
	D81911	10 x 50 ml
	D0438917	9 x 65 ml
	DK0740	5 x 50 ml
	DA0843	5 x 50 ml
	DT1043	4 x 50 ml
	DE1843	10 x 50 ml

	REF	CONT
Sodium, *Enzymatic*	914605	5 x 100 ml
	914607	6 x 25 ml
	909610	3 x 20 ml
	990911	1 x 60 ml
	9A0852	3 x 20 ml
	9T1052	3 x 20 ml
	9E1852	2 x 60 ml
UIBC, *Ferene*	D07300B	1 x 12,5 L
	D07310B	1 x 1 L
	D07320	5 x 100 ml
	D07330	5 x 50 ml
	D07340	5 x 25 ml
	D07350	5 x 10 ml
	D86911	5 x 50 ml
	D0444917	5 x 62,5 ml
	D1444917	350 ml
	DK0741	5 x 50 ml
	DA0844	5 x 50 ml
	DT1044	4 x 62,5 ml
	DE1844	2 x 62,5 ml
Urea UV Auto, *Urease/GLDH*	D03121B	1 x 1,25 L
	D95704	5 x 100 ml
	D10704	5 x 100 ml
	D98707	5 x 50 ml
	D10707	5 x 50 ml
	D00715	5 x 25 ml
	D00716	5 x 10 ml
	D82911	10 x 50 ml
	D0439917	5 x 62,5 ml
	DK0742	5 x 50 ml
	DA0845	5 x 50 ml
	DT1045	4 x 62,5 ml
	DE1845	4 x 62,5 ml
Urea, *Urease/colorimetric*	402999	5 x 100 ml
	413925	6 x 25 ml
Uric Acid AOX, *Enzymatic, colorimetric*	D94710	5 x 100 ml
	D98714	5 x 50 ml
	D00719	5 x 25 ml
	D00720	5 x 10 ml
	D84911	10 x 50 ml
	D0440917	5 x 62,5 ml
	DK0743	5 x 50 ml
	DA0846	5 x 50 ml
	DT1046	4 x 62,5 ml
	DE1846	8 x 62,5 ml

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Addendum to the Declaration of Conformity for Devices other than those covered by Annex II (Clinical Chemistry)

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Calibrators

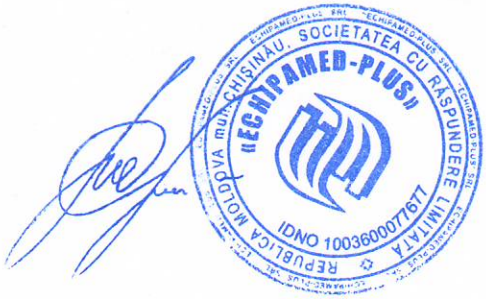
	REF	CONT
Diacal Auto	D98485	5 x 3 ml
	D98485SV	1 x 3 ml
Diacal Lipids	D13585SV	1 x 2 ml
Diacal CK-MB	D13595	5 x 1 ml
	D13595SV	1 x 1 ml
ADA Calibrator	913870SV	1 x 1 ml
G6PDH Calibrator	Y17565SV	1 x 0,5 ml
Homocysteine Calibrator Set (5 levels)	908550	5 x 1 ml
Ethanol Calibrator/Control Set	Z05880	4 x 1 ml
HDL-Cholesterol Calibrator	F03710SV	1 x 3 ml
LDL-Cholesterol Calibrator	F03711SV	1 x 1 ml
Hemoglobin Total Calibrator	Y04705SV	1 x 2 ml

Standards

	REF	CONT		REF	CONT
Albumin Standard	D95555	1 x 3 ml	Lithium Standard Set (3 levels)	910280	3 x 3 ml
Ammonia Standard	Y08310SV	1 x 5 ml	Lithium Standard Set (5 levels)	910285	5 x 3 ml
Bile Acids Standard	903210	1 x 3 ml	Magnesium Standard	D95339	1 x 3 ml
Calcium Standard	D95094	1 x 3 ml	NEFA Standard	D07963SV	1 x 3 ml
Chloride Standard	D95108	1 x 3 ml	Phosphorus Standard	D95362	1 x 3 ml
Cholesterol Standard	D95114	1 x 3 ml	Potassium Standard Set (2 levels)	910180	2 x 3 ml
CO2 Standard	D06520SV	1 x 3 ml	Protein Total Standard	D94683	1 x 3 ml
Copper Standard	507163SV	1 x 3 ml	Protein Total in Urine/CSF Standard	D03600	1 x 3 ml
Creatinine Standard	D94592	1 x 3 ml	Sodium Standard Set (2 levels)	909680	2 x 3 ml
Glucose Standard	D95223	1 x 3 ml	Triglycerides Standard	D95380	1 x 3 ml
beta-Hydroxybutyrate Standard	D10090SV	1 x 3 ml	Urea Standard	D95706	1 x 3 ml
Iron Standard	D95305	1 x 3 ml	Uric Acid Standard	D94708	1 x 3 ml
			Zinc Standard	507263SV	1 x 3 ml

Controls

	REF	CONT		REF	CONT
Diacon N	D98481	12 x 5 ml	Diacon Urine Level 1	D08581	12 x 5 ml
	D14481	5 x 5 ml		D08581SV	1 x 5 ml
	D98481SV	1 x 5 ml	Diacon Urine Level 2	D08582	12 x 5 ml
Diacon P	D98482	12 x 5 ml		D08582SV	1 x 5 ml
	D14482	5 x 5 ml	ADA Control Set (2 levels)	913880	2 x 1 ml
	D98482SV	1 x 5 ml	Ammonia Control Set (2 levels)	Y08330	2 x 5 ml
Diacon Lipids	D99486	3 x 3 ml	G6PDH Control Set (3 levels)	Y17560	6 x 0,5 ml
	D99486SV	1 x 3 ml	Hemoglobin Total Control Set	Y04706	6 x 2 ml
Diacon Lipids High	D11487	3 x 3 ml	(3 levels)		
	D11487SV	1 x 3 ml	Homocysteine Control Set (4 levels)	905620	4 x 1 ml
CO2 Control	D16525	3 x 3 ml	Lithium Control Set (2 levels)	910290	2 x 3 ml
	D16525SV	1 x 3 ml	Potassium Control Set (2 levels)	910190	2 x 3 ml



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