

AUTHORIZATION LETTER

Wr. Neudorf, 09.02.2021

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 01.01.2021 until 31.01.2022 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



DIALAB
Produktion und Vertrieb von chemisch-technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
A-2351 Wr. Neudorf, Hondastrasse Obj. M55
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Christina ERNST
Export Manager



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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



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

Stefan Preiß

Date, 2019-03-28



EC 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 (Coagulation), Rev.08 (1 page)", classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

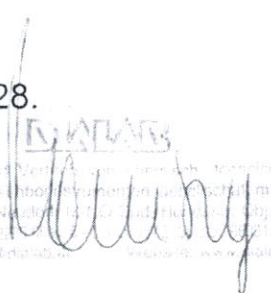
Devices other than those covered by Annex II (Coagulation)

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 there are any major changes in the corresponding Technical Documentation.

This Declaration is valid until 2022-03-28.


Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m. b. H.
A – 2351 Wr. Neudorf, Objekt M55
Phone +43(0)2236 2351
E-Mail: office@dialab.at

Wr. Neudorf, 2019-04-08



DI Marlene Ramsey
Managing Director

**Addendum to the Declaration of Conformity for Other Products
(Coagulation)**



COAGULATION AND FIBRINOLYSIS

	REF	CONT
APTT (Activated Partial Thromboplastin Time)		
APTT-S liquid	T085420	10x 5 mL
	T085450	10x 10 mL
APTT-EA liquid		
	C01130	5x 8 mL
	C01130SV	1x 8 mL
	C14130	2x 5 mL APTT EA liquid 2x 5 mL CaCl ₂
Calcium Chloride, 0.025 M		
	C03100	5x 10 mL
Calcium Chloride, 0.020 M		
	C03100SV	1x 10 mL
	C03101	5x 10 mL
PT (Prothrombin Time)		
Thromboplastin liquid		
	T126115	5x 2 mL
	T126110	5x 4 mL
Thromboplastin-S		
	T955221	10x 5 mL (lyo.), incl. solvent
	T955251	10x 10 mL (lyo.), incl. solvent
FIB (Fibrinogen)		
Fibrinogen Kit		
	T955500	400 tests
Human Thrombin		
	T955502	10x 2 mL (lyo.)
	T955555	10x 5 mL (lyo.)
Imidazole Buffered Saline		
	T955504	2x 125 mL
TT (Thrombin Time)		
Thrombin Time (TT)		
	T955560	5x 3 mL (lyo.)
D-Dimer		
D-Dimer Latex Agglutination Kit		
	T9515707	80 tests
D-Dimer for DIAcheck & Coalyser		
	T099702	62 tests
	T099703	125 tests
Reference Plasma		
Normal Coagulation Reference Plasma		
	T955105	10x 1 mL (lyo.)
Special Calibration Plasma		
	T155105	10x 1 mL (lyo.)
Control Plasmas		
Normal Coagulation Control Plasma		
	T955100	10x 1 mL (lyo.)
Abnormal Coagulation Control Plasma		
	T955101	10x 1 mL (lyo.)
Special Control Plasma Normal		
	T155100	10x 1 mL (lyo.)
Special Control Plasma Abnormal		
	T155101	10x 1 mL (lyo.)
Coagulation Factors		
Deficient Plasma Factor II		
	T994702	10x 1 mL (lyo.)
Deficient Plasma Factor V		
	T994705	10x 1 mL (lyo.)
Deficient Plasma Factor VII		
	T994707	10x 1 mL (lyo.)
Deficient Plasma Factor VIII		
	T994708	10x 1 mL (lyo.)
Deficient Plasma Factor IX		
	T994709	10x 1 mL (lyo.)
Deficient Plasma Factor X		
	T994710	10x 1 mL (lyo.)
Deficient Plasma Factor XI		
	T994711	10x 1 mL (lyo.)
Deficient Plasma Factor XII		
	T994712	10x 1 mL (lyo.)
Protein C & S		
Protein C Kit		
	T954133	480 tests
Protein S Kit		
	T984345	80 tests

