

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.

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
	C03100SV	1x 10 mL
Calcium Chloride, 0.020 M	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.)
	T955504	2x 125 mL
Imidazole Buffered Saline		
TT (Thrombin Time)		
Thrombin Time (TT)	T955560	5x 3 mL (lyo.)
D-Dimer		
D-Dimer Latex Agglutination Kit	T9515707	80 tests
D-Dimer for DLAcheck & 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

