technoclone TC	**Declaration of Conformity** European Directive 98/79/EC Attachment 3 of DO0081 i.t.c.v.	Dok.Nr.:TF0003.03 Ersetzt: TF0003.02

Manufacturer: Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Brunner Str. 67
1230 Vienna
AUSTRIA

Product: **valid from LOT :**

REF 5344512 APC Control Kit, 2 x 1 ml 0C65000

Classification: IVD, "all other classes"

European directive: 98/79/EC

We declare that the above mentioned products meets all applicable requirements set out in Annex III (excluding section 6) of the Directive 98/79/EC and take sole responsibility of the these products. These products have been manufactured and classified as "all other classes" according to the European Directive 98/79/EC.

CE

Date: 20-May-2022
Valid until: 26-May-2027

V. Binder
Company director

S. Schwingenschlögl
QM-Manager

Amendment to Declaration of Conformity

European Directive 98/79/EC

Temp.: TF0361.03

Pursuant to Article 110 (3b) of EU 2017/746 (IVDR) concerning in vitro diagnostic medical devices, amended through Regulation (EU) 2024/1860, the validity of the Declaration of Conformity is adapted to comply with the transitional provisions.

Manufacturer: Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH

Brunnerstrasse 67

1230 Vienna, Austria

This amendment confirms and extends the validity of the respective Declaration of Conformity (IVDD) for Class B devices until 31.12.2029 (Art. 110 (3b) (c)) and Class C devices until 31.12.2028 (Art. 110 (3b) (b)). It is only valid in combination with the following EC Declaration of Conformity (IVDD):

Class B Devices:

5344512	APC Control Kit 2x1 ml
5344510	APC Resistance Kit - TC 120 T.
5344515	APC Resistance Kit - TC 40 T.
5114008	F II Mangelplasma immundepleted 5x1 ml
5134004	F V Mangelplasma, immunads 5x1 ml
5144015	F VII Mangelplasma, immunads 5x1 ml
5174006	F X Mangelplasma, immundepl. 5x1 ml
5174004	F X Mangelplasma, nativ 5x1 ml
5184006	F XI Mangelplasma, immunads., 5x1 mL
5184004	F XI Mangelplasma, nativ 5x1 ml
5194007	F XII Mangelplasma, immunads., 5x1 mL
5194008	F XII Mangelplasma, nativ 5x1 ml
5204006	Fitzgerald Trait Plasma 2x1 ml
5343005	Lupus Anticoagulant Test 6 T.
5343010	Lupus Inhibitorplasma 2x1 ml
5343019	Lupus Inhibitorplasma 5x1 ml
5343022	Platelet Poor Plasma 5x2 ml
5343021	Lupus Inhibitorplasma Low 5x1 ml
5205006	Fletcher Trait Plasma 2x1 ml
5346806	Protein C Mangelplasma 2x1 ml
5341031	Protein S deficient plasma immunodepleted
5345003	Technochrom C1-Inhibitor 30 T.
5345004	Technochrom C1 INH 2G
5360010	Technochrom FXIII 3x3 ml
5342631	Technochrom Plasmin INH
5340251	Technochrom Plasminogen
5341013	Technochrom Protein C 30 T.
5341014	Technochrom Protein C 2G
5343052	Technoclot® DRVVT Confirm
5343050	Technoclot® DRVVT Screen
5343056	Technoclot Ecarin

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5343016	Technoclot LA Confirm 5x1 ml
5343012	Technoclot LA Screen 5x2 ml
5343058	Technoclot Lupus aPTT
5343060	Technoclot Lupus aPTT
5346200	Technoclot Protein C
5341030	Technoclot Protein S
5343054	Technoclot Taipan
4848200	Technoleia Free Protein S
4848300	Technoleia VWF:Ag
4848310	Technoleia VWF:Ag CAL Set
5700100	TECHNOSCREEN ADAMTS-13 Activity
5450601	Technozym ADAMTS-13 Antigen, 96 T.
5450661	Technozym ADAMTS-13 Calibrator Set, 5 x 0.5 mL
5450663	Technozym ADAMTS-13 Control Set, 2 x 0.5 mL
5450401	Technozym ADAMTS-13 INH, 96 T.
5450451	Technozym ADAMTS-13 INH, 48 T.
5450461	Technozym ADAMTS-13 INH Calibrator Set, 5 x 0,5 ml
5450463	Technozym ADAMTS-13 INH Control Set 2 x 0,5 ml
TC16075	Technozym PAI-1 Actibind ELISA Kit 96 T. (new)
TC16077	Technozym PAI-1 Actibind Calibrator Set, 5 x 0.5 mL
TC16079	Technozym PAI-1 Actibind Control Set, 2 x 0.5 mL
TC12075	Technozym PAI-1 ELISA Kit 96 T. (new)
TC12077	Technozym PAI-1 Antigen Calibrator Set, 5 x 0.5 mL
TC12079	Technozym PAI-1 Antigen Control Set, 2 x 0.5 mL
TC12021	Technozym Protein C ELISA 96 T.
TC12007	Technozym t-PA Ag EDTA ELISA
TC12001	Technozym t-PA Antigen Calibrator Set, 5 x 0,5 mL
TC12003	Technozym t-PA Antigen Control Set, 2 x 0,5 mL
5450201	Technozym vWF:Ag ELISA 96 T.
5450210	Technoyzm vWF:Ag Calibrator Set, 5 x 0,5 mL
5450212	Technoyzm vWF:Ag Control Set, 2 x 0,5 mL

Class C Devices:

5010004	Ak-Calibrant 4x1 ml
5010024	AK-Verification Kit, 3 x 1 ml
5006347	Ceveron TGA CAL Set, 1 Set
5006011	Ceveron TGA RB Kit, 120 T.
5006015	Ceveron TGA RC High Kit, 120 T.
5006013	Ceveron TGA RC Low Kit, 120 T.
5021055	Coagulation Control A 5x1 ml
5021060	Coagulation Control A 50x1 ml
5011050	Coagulation Control AK 5x1 ml
5011060	Coagulation Control AK 50x1 ml
5020040	Coagulation Control N 5x1 ml

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5020050	Coagulation Control N 50x1 ml
5220110	Coagulation Reference 5x1 ml
5220120	Coagulation Reference 50x1 ml
5035060	Dapttin TC 5x2 ml
5035090	Dapttin TC 6x10 ml
5035100	Dapttin TC 20x10 ml
5164003	F IX Mangelplasma immundepl. 5x1 ml
5164004	F IX Mangelplasma immundepl. 50x1 ml
5164008	F IX Mangelplasma, nativ 5x1 ml
5164016	F IX Mangelplasma, nativ 50x1 ml
5154002	F VIII Mangelplasma immunads. 5x1 ml
5154004	F VIII Mangelplasma immunads. 50x1ml
5154007	F VIII Mangelplasma, nativ 5x1 ml
5154016	F VIII Mangelplasma, nativ 50x1 ml
5159010	F VIII Inhibitorplasma HCV neg. 5x1 ml
5159008	F VIII Inhibitorplasma 5x1 ml
5152009	F VIII Inhibitor Reagenziensatz HCV neg. 2-4 T.
5152005	F VIII Inhibitor Reagenziensatz 2-4 T.
5138080	Fibrinogen Reagenz (120 T.) 5x5 ml
5138085	Fibrinogen Reagenz 5x2 ml
5138005	Fibrinogen Reagent kit 45 T.
5035118	Siron LIS(aPTT liquid) 2x4 ml
5035119	Siron LIS (aPTT liquid) 10x4 ml
5035121	Siron LIS (aPTT liquid) 10x10 ml
5035105	Siron LS(aPTT liquid) 2x4 ml
5035107	Siron LS (aPTT liquid) 10x4 ml
5035109	Siron LS (aPTT liquid) 10x10 ml
5340250	Technochrom anti Xa Kit 80.T
5340224	Technochrom AT III Kit 80 T.
5340225	Technochrom AT III manual method Kit ~ 39 T.
5347000	Technochrom DTI
5344101	Technochrom FVIII:C 40 T.
5344102	Technochrom FVIII 2G
5344104	Technochrom FVIII 2G CAL Set
5021070	Technoclot Control A, 10 x 1 ml
5021075	Technoclot Control A, 50 x 1 ml
5021062	Technoclot Control A2, 10 x 1 ml
5021064	Technoclot Control A2, 50 x 1 ml
5020070	Technoclot Control N, 10 x 1 ml
5020075	Technoclot Control N, 50 x 1 ml
5100025	Technoclot DTI Kit, 2 x 20 T.
5005044	Technoclot PT Owren automated 10x4 mL
5005046	Technoclot PT Owren automated 10x10 ml
5005100	Technoclot PT Owren Capillary Calibration Set

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5005102	Technoclot PT Owren Capillary Control Set
5005032	Technoclot PT Owren manual 10x4 mL
5005037	Technoclot PT Owren manual 10x10 ml
5003220	Technoclot PT PLUS 5x4 ml
5003222	Technoclot PT PLUS 10x10 ml
5800100	Technofluor ADAMTS13 Activity 25 T.
5800102	Technofluor ADAMTS13 Activity 0 CAL 2x1 ml
5800200	Technofluor FXIII Activity
4847200	TechnoLEIA D-Dimer Latex Kit 150 T.
4847210	TechnoLEIA D-Dimer Latex Kit 50 T.
4847236	TechnoLEIA D-Dimer Calibrator 0 ng/ml 2 x 1 mL
4847234	TechnoLEIA D-Dimer Calibrator 3000 ng/ml 2 x 1 mL
4847230	TechnoLEIA D-Dimer Control high 5x1 ml
4847232	TechnoLEIA D-Dimer Low Control 5 x 1 mL
4848100	Technoleia FDP
4848110	Technoleia FDP CAL Set
4848120	Technoleia FDP CON Set
5003009	Technoplastin HIS 12x2 ml
5003021	Technoplastin HIS 20x10 ml
5003026	Technoplastin HIS 6x10 ml
5003030	Technoplastin HIS 2x10 ml
5003010	Technoplastin HIS, 12x4 ml f. Ceveron
5003022	Technoplastin HIS, 20x20 ml f. Ceveron
5003028	Technoplastin HIS, 6x20 ml f. Ceveron
5090280	Technoview allXa CON Set
5090269	TECHNOVIEW Apixaban CAL 5x1 ml
5090270	TECHNOVIEW Apixaban CONT H 5x1 ml
5090271	TECHNOVIEW Apixaban CONT L 5x1 ml
5090140	TECHNOVIEW Argatroban CAL Set 5x1 ml
5090144	TECHNOVIEW Argatroban CONT H 5x1 ml
5090142	TECHNOVIEW Argatroban CONT L 5x1 ml
5090010	TECHNOVIEW Arixtra CAL 5x1 ml
5090014	TECHNOVIEW Arixtra CONT H 6x1 ml
5090012	TECHNOVIEW Arixtra CONT L 6x1 ml
5090210	TECHNOVIEW Dabigatran CAL 5x1 ml
5090212	TECHNOVIEW Dabigatran CONT H 5x1 ml
5090214	TECHNOVIEW Dabigatran CONT L 5x1 ml
5090250	TECHNOVIEW Edoxaban CAL Set 5x1 ml
5090253	TECHNOVIEW Edoxaban CONT High 5x1 ml
5090251	TECHNOVIEW Edoxaban CONT Low 5x1 ml
5090252	TECHNOVIEW Edoxaban CONT Medium 5x1 ml
5090040	TECHNOVIEW LMW CAL 5x1 ml
5090046	TECHNOVIEW LMW High Control 5x1 ml
5090042	TECHNOVIEW LMW Low Control 5x1 ml

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5090044	TECHNOVIEW LMW Medium Control 5x1 ml
5090110	TECHNOVIEW Orgaran CAL 5x1 ml
5090114	TECHNOVIEW Orgaran CONT H 5x1 ml
5090112	TECHNOVIEW Orgaran CONT L 5x1 ml
5090170	TECHNOVIEW Rivaroxaban CAL 5x1 ml
5090171	TECHNOVIEW Rivaroxaban CAL High 5x1 ml
5090174	TECHNOVIEW Rivaroxaban CONT H 5x1 ml
5090172	TECHNOVIEW Rivaroxaban CONT L 5x1 ml
5090173	TECHNOVIEW Rivaroxaban CONT M 5x1 ml
5090070	TECHNOVIEW UFH CAL 5x1 ml
5090074	TECHNOVIEW UFH CONT H 5x1 ml
5090072	TECHNOVIEW UFH CONT L 5x1 ml
5450701	Technozym ADAMTS-13 Activity ELISA, 96 T.
5450761	Technozym ADAMTS-13 Activity CAL Set, 5 x 0.5 mL
5450763	Technozym ADAMTS-13 Activity CONT Set, 2 x 0.5 mL
5450501	Technozym ADAMTS-13, 2 x 48 T.
5450551	Technozym ADAMTS-13, 48 T.
5450561	Technozym ADAMTS-13 Calibrator Set, 5 x 0.5 mL
5450563	Technozym ADAMTS-13 Control Set, 2 x 0.5 mL
2599006	Technozym D-Dimer ELISA Kit, 96 T.
5450310	Technozym vWF:CBA Calibration Set, 5 x 0,5 mL
5450312	Technozym vWF:CBA Control Set, 2 x 0,5 mL
5450311	Technozym vWF:CBA Collagen Typ I, 96 T.
5450301	Technozym vWF:CBA ELISA 96 T.
5100005	Thrombin Reagent (6x6 ml) 180 T.

Veronika Binder

Company Director

Vienna, 19.08.2024

Lara Schöllbauer

Head of Regulatory Affairs

Vienna, 19.08.2024

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