

DECLARATION OF CONFORMITY

- 1) Manufacturer (Name, Department): Alfa Wassermann Diagnostic Technologies LLC
Address: 4 Henderson Drive
West Caldwell, NJ 07008
USA

and

- 2) European Authorized Representative: Alfa Wassermann B.V., The Netherlands
Address: Pompmolenlaan 24
3447 GK Woerden
The Netherlands

- 3) Products:

ACE Series (ACE, ACE Alera) Clinical Chemistry Analyzer
Starlyte V Electrolyte Analyzer
and Accessories

see appendix: I

- 4) The products described above are in conformity with:

Title	Document Number	Date of Issue
In vitro Diagnostic Medical Devices Directive	98/79/EC As amended (EC) No 1882/2003	1998-10-27 2003-09-29

- 5) Additional Information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity Assessment Procedure for CE Marking In vitro Diagnostic Medical Device Directive, Annex III

Woerden, 2011-03-17

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Paul Heerdt, Q.A.

Paul Heerdt

(Place and date of issue: yyyy-mm-dd) (Name; title and signature of authorized representative)

Appendix I.

List of products intended for *In Vitro* Diagnostic Application.

Date of Issue

SA1029 -----	STANDARD A FOR DIRECT ISE	05-11-2003
E1-2 -----	STANDARD B FOR DIRECT ISE	05-11-2003
SA1039 SA2039 -----	CARBON DIOXIDE	05-11-2003
SA1021 -----	SYSTEM DILUENT	05-11-2003
SA1028 -----	CLEANING/CONDITIONER	05-11-2003
E1-3 -----	REFERENCE SOLUTION FOR ISE	05-11-2003
SA1027 -----	ISE WASH	05-11-2003
E1-8 -----	FLUID PACK STARLYTE III	05-11-2003
E1-9 -----	FLUID PACK STARLYTE V	30-01-2008
E1-5 -----	CLEANING SOLUTION STARLYTE	05-11-2003
E1-6 -----	SODIUM CONDITIONER STARLYTE	05-11-2003
E1-7 -----	URINE DILUENT	05-11-2003
39-10700-18 -----	(ACE Series), ACE ANALYZER SYSTEM	05-11-2003
402900 -----	(ACE Series), ACE ALERA ANALYZER SYSTEM	26-08-2004
908407-1 -----	STARLYTE V	05-11-2003
903393 -----	SODIUM (Na) ELECTRODE ACE, STARLYTE	05-11-2003
903394 -----	POTASSIUM (K) ELECTRODE ACE, STARLYTE	05-11-2003
906178 -----	CHLORIDE (Cl) ELECTRODE ACE, STARLYTE	05-11-2003
908424 -----	LITHIUM (Li) ELECTRODE, STARLYTE V	05-11-2003
908425 -----	CALCIUM (Ca) ELECTRODE, STARLYTE V	05-11-2003
906179 -----	REFERENCE ELECTRODE ACE, STARLYTE	05-11-2003
903396 -----	REFERENCE ELECTRODE HOUSING ACE	05-11-2003
906185 -----	REFERENCE ELECTRODE HOUSING STARLYTE	05-11-2003
ACD-2(E) -----	REACTION CUVETTES	05-11-2003
ACD-4 -----	BIOBAGS	05-11-2003
ACD-6(E) -----	SAMPLE CUPS	05-11-2003
ACD-3 -----	SEGLETS, 10 WELLS	05-11-2003
ACD-5 -----	EVAPORATION CAPS	05-11-2003

These products are registered (FORM 10) and can be sold in the following countries:

Belgium
Bulgaria
Germany
Spain
UK + Ireland
Italy
Lithuania
The Netherlands

Portugal
Romania
Swiss
Greece
Poland

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DECLARATION OF CONFORMITY

- 1) Manufacturer (Name, Department): Alfa Wassermann B.V., The Netherlands
Address: Pompmolenlaan 24
3447 GK Woerden
The Netherlands

- 2) Products:

Reagents for ACE series (ACE, ACE Alera, NExCT) Clinical Chemistry Analyzers

see appendix: I

- 3) The products described above are in conformity with:

Title	Document Number	Date of Issue
In vitro Diagnostic Medical Devices Directive	98/79/EC As amended (EC) No 1882/2003	1998-10-27 2003-09-29

- 4) Additional Information (conformity procedure, Notified Body, CE certificate, etc.):

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Woerden, 2003-09-29
(Place and date of issue: yyyy-mm-dd) (Name; title and signature of manufacturer)

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for Heerdt, QA
J. G. J. Heerdt

Appendix I.

List of products intended for *In Vitro* Diagnostic Application.

Date of Issue

AE5-2-----	ALBUMIN	05-11-2003
NE5-2-----	ALBUMIN	05-11-2003
AE1-3-----	ALKALINE PHOSPHATASE	05-11-2003
AE2-5c-----	AMYLASE	05-11-2003
AE1-7-----	DIRECT BILIRUBIN	05-11-2003
NE1-7-----	DIRECT BILIRUBIN	05-11-2003
AE2-8-----	BILIRUBIN TOTAL	05-11-2003
NE2-8-----	BILIRUBIN TOTAL	05-11-2003
AE5-10-----	CALCIUM	05-11-2003
NE5-10-----	CALCIUM	05-11-2003
AE2-12-----	CHOLESTEROL	05-11-2003
NE2-12-----	CHOLESTEROL	05-11-2003
AE1-13-----	CK	05-11-2003
AE1-40-----	CKMB	05-11-2003
ER3-34-----	CHOLESTEROL HDL – PRECIPITATION REAGENT	05-11-2003
AE2-15-----	CREATININE	05-11-2003
NE2-15-----	CREATININE	05-11-2003
AE1-36-----	GOT/AST IFCC	05-11-2003
AE1-34-----	GPT/ALT IFCC	05-11-2003
AE1-16-----	GAMMA-GT	05-11-2003
AE2-17-----	GLUCOSE HK (HEXOKINASE)	05-11-2003
AE2-27-----	GLUCOSE PAP	05-11-2003
NE2-27-----	GLUCOSE PAP	05-11-2003
AE5-18-----	INORGANIC PHOSPHORUS	05-11-2003
NE5-18-----	INORGANIC PHOSPHORUS	05-11-2003
AE2-33/NAE2-33-----	IRON	05-11-2003
AE2-43/NAE2-43-----	UIBC	05-11-2003
AE1-20-----	LDH-P	05-11-2003
LE1-20-----	LDH-P	05-11-2003
AE1-22-----	MAGNESIUM	05-11-2003
AE5-23-----	TOTAL PROTEIN	05-11-2003
NE5-23-----	TOTAL PROTEIN	05-11-2003
AE2-24-----	TRIGLYCERIDES	05-11-2003
NE2-24-----	TRIGLYCERIDES	05-11-2003
AE5-9-----	UREA/BUN	05-11-2003
NE5-9-----	UREA/BUN	05-11-2003
LE5-9-----	UREA/BUN	05-11-2003
AE2-25-----	URIC ACID	05-11-2003
NE2-25-----	URIC ACID	05-11-2003

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List of products intended for *In Vitro* Diagnostic Application.

Registered

AE1-51	CHOLESTEROL HDL DIRECT	05-11-2003
AE1-53	CHOLESTEROL HDL DIRECT	05-11-2003
AE1-52	LDL-CHOLESTEROL REAGENT	30-01-2004
AE1-50	HbA1c	05-11-2003
ES1-51	CHOLESTEROL HDL/LDL CALIBRATORS	05-11-2003
EC1-51	CHOLESTEROL HDL/LDL CONTROL LOW	05-11-2003
EC1-52	CHOLESTEROL HDL/LDL CONTROL HIGH	05-11-2003
ES1-50	HbA1c CALIBRATORS	05-11-2003
EC1-50	HbA1c CONTROLS	05-11-2003
ES1-20	GEMCAL CALIBRATOR	05-11-2003
EC10-1	LEVEL 1 CHEMISTRY CONTROL LOW	05-11-2003
EC10-2	LEVEL 2 CHEMISTRY CONTROL ELEVATED	05-11-2003
ASD-E	SYSTEM DILUENT REFILL	05-11-2003
ASP-6	CRP	05-11-2003
ASP-7	ASO	05-11-2003
ASP-7(C)	ASO	05-11-2003
ASP-8(C)	RF	05-11-2003
ASP-9(C)	FERRITIN	05-11-2003
SPC-6	MULTI-CALIBRATOR SET CRP	05-11-2003
SPC-4	CALIBRATOR ASO	05-11-2003
SPC-5	CALIBRATOR SET RF	05-11-2003
ECP-1	SPECIAL PROTEIN CONTROL LOW	05-11-2003
ECP-2	SPECIAL PROTEIN CONTROL ELEVATED	05-11-2003
ECP-3	CONTROL ASO	05-11-2003
ECP-4	CONTROL RF	05-11-2003
05760288	SPECIAL PROTEINS CALIBRATOR SET	05-11-2003
05760199	IGA	05-11-2003
05760210	IGG	05-11-2003
05760211	IGM	05-11-2003
05760214	TRANSFERRIN	05-11-2003
05760032	MICRO ALBUMIN	05-11-2003
05760283	MICRO-ALBUMIN CALIBRATOR SET	05-11-2003
05760282	CONTROL MICRO ALBUMIN	05-11-2003
05760047	IMMUNO DILUENT	05-11-2003

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Portugal
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Greece
Poland