

Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 97/79/EC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for:

**LuSys Laboratories
10054 Mesa Ridge Court - Suite 118
San Diego CA 92121
United States**

as stipulated and demanded by the aforementioned Directive.
The Dutch Competent Authorities have accepted the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

See appendix with further product/model information

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the IVD medical devices fulfil the essential requirements of Directive 98/79/EC.

2010-01-21


M. de Jong
CEpartner4U BV

C e p a r t n e r 4 U

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Appendix to Certificate of CE-Registration

List of devices.

Device name	<u>Type/ model/ref number</u>	Risk class	EDMS-code	First date of CE-marking
ELISA				
Troponin I	7001	Low risk	1213010700	2010-01-19
Myoglobin	7002	Low risk	1213010500	2010-01-19
CKMB	7003	Low risk	1213010200	2010-01-19
FSH	1001	Low risk	1205010400	2010-01-19
hCG	1002	Low risk	1205020500	2010-01-19
hGH	1003	Low risk	1206040200	2010-01-19
LH	1004	Low risk	1205010500	2010-01-19
Progesterone	1005	Low risk	1205010600	2010-01-19
Prolactin	1006	Low risk	1205010800	2010-01-19
Testosterone	1007	Low risk	1205011000	2010-01-19
Estradiol	1008	Low risk	1205010300	2010-01-19
Insulin	1009	Low risk	1206010300	2010-01-19
C-Peptide	1010	Low risk	1206010100	2010-01-19
Visual hCG	1012	Low risk	1205020500	2010-01-19
<i>B-hCG</i>	1013	Low risk	1205020500	2010-01-19
Cortisol	1014	Low risk	1206020400	2010-01-19
AFP	2001	Low risk	1203900100	2010-01-19
B2 Microglobulin	2002	Low risk	1203900200	2010-01-19
CA-125	2003	Low risk	1203010600	2010-01-19
CA-153	2004	Low risk	1203010200	2010-01-19
CA-199	2005	Low risk	1203010300	2010-01-19
CEA	2006	Low risk	1203013100	2010-01-19
Free B-hCG	2007	Low risk	1205020600	2010-01-19
T-3	3001	Low risk	1204010500	2010-01-19

Device name	Type/ model/ref number	Risk class	EDMS-code	First date of CE-marking
T-4	3002	Low risk	1204010700	2010-01-19
TSH	3003	Low risk	1204011100	2010-01-19
Ultrasensitive TSH	3004	Low risk	1204011100	2010-01-19
Free T4	3005	Low risk	1204010200	2010-01-19
Free T3	3006	Low risk	1204010100	2010-01-19
H. Pylori IgG	4007	Low risk	1501040300	2010-01-19
H. Pylori IgM	4008	Low risk	1501040300	2010-01-19
HSV I IgG	4013	Low risk	1504030800	2010-01-19
HSV I IgM	4014	Low risk	1504030900	2010-01-19
HSV II IgG	4015	Low risk	1504031100	2010-01-19
HSV II IgM	4016	Low risk	1504031200	2010-01-19
EBV VCA IgG EB	4026	Low risk	1504049000	2010-01-19
EBV VCA IgM EB	4027	Low risk	1504049000	2010-01-19
SYPHILIS ELISA	4044	Low risk	1501030300	2010-01-19
CHAGAS	4045	Low risk	1505100200	2010-01-19
H. Py Antigen (Feces)	4046	Low risk	1501040300	2010-01-19
DENGUE IgG	4047	Low risk	1504401100	2010-01-19
DENGUE IgM	4048	Low risk	1504401100	2010-01-19
BRUCELLA IgG	4054	Low risk	1501400100	2010-01-19
BRUCELLA IgM	4055	Low risk	1501400100	2010-01-19
ANA	5001	Low risk	1210010100	2010-01-19
dsDNA	5002	Low risk	1210010500	2010-01-19
RF IgM	5003	Low risk	1211011000	2010-01-19
CRP	5004	Low risk	1213019000	2010-01-19
ANTI-TIPO	5005	Low risk	1210900100	2010-01-19
ANTI-TG ELISA Kit	5006	Low risk	1204010800	2010-01-19
Ferritin	6001	Low risk	1207010200	2010-01-19
IgE	6002	Low risk	1202010200	2010-01-19
CHEMILUMINESCENCE				
FSH CLIA Kit	7001	Low risk	1205010400	2010-01-19
hCG CLIA Kit	7002	Low risk	1205020500	2010-01-19

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hGH CLIA Kit	7003	Low risk	1205020500	2010-01-19
LH CLIA Kit	7004	Low risk	1205010500	2010-01-19
Progesterone CLIA Kit	7005	Low risk	1205010600	2010-01-19
Prolactin CLIA Kit	7006	Low risk	1205010800	2010-01-19
Testosterone CLIA Kit	7007	Low risk	1205011000	2010-01-19
Estradiol CLIA Kit	7008	Low risk	1205010300	2010-01-19
Insulin CLIA Kit	7009	Low risk	1206010300	2010-01-19
C-Peptide CLIA Kit	7010	Low risk	1206010100	2010-01-19
AFP CLIA Kit	8001	Low risk	1203900100	2010-01-19
B2 Microglobulin CLIA	8002	Low risk	1203900200	2010-01-19
CA-125 CLIA Kits	8003	Low risk	1203010600	2010-01-19
CA-153 CLIA Kit	8004	Low risk	1203010200	2010-01-19
CA-199 CLIA Kit	8005	Low risk	1203010300	2010-01-19
CEA CLIA Kit	8006	Low risk	1203013100	2010-01-19
Free BhCG CLIA Kit	8007	Low risk	1205020600	2010-01-19
Free PSA CLIA Kit	8008	Low risk	1203013300	2010-01-19
PSA CLIA Kit	8009	Low risk	1203013200	2010-01-19
NSE CLIA Kit	8010	Low risk	1203900800	2010-01-19
T-3 CLIA Kit	9001	Low risk	1204010500	2010-01-19
T-4 CLIA Kit	9002	Low risk	1204010700	2010-01-19
TSH CLIA Kit	9003	Low risk	1204011100	2010-01-19
Ultrasensitive TSH CLIA Kit	9004	Low risk	1204011100	2010-01-19
free T4 CLIA Kit	9005	Low risk	1204010200	2010-01-19
free T3 CLIA Kit	9006	Low risk	1204010100	2010-01-19
HSV I IgG CLIA Kit	10013	Low risk	1504030800	2010-01-19
HSV I IgM CLIA Kit	10014	Low risk	1504030900	2010-01-19
HSV II IgG CLIA Kit	10015	Low risk	1504031100	2010-01-19
HSV II IgM CLIA Kit	10016	Low risk	1504031200	2010-01-19
H.Py IgG CLIA Kit	10031	Low risk	1501040300	2010-01-19
Ferritin CLIA Kit	11001	Low risk	1207010200	2010-01-19

Device name	Type/ model/ref number	Risk class	EDMS-code	First date of CE-marking
IgE CLIA Kit	11002	Low risk	1202010200	2010-01-19
CRP CLIA Kit	11003	Low risk	1213019000	2010-01-19
Rapid Test				
Tni	H-001	Low risk	1213010700	2010-01-19
Tni	H-002	Low risk	1213010700	2010-01-19
CKMB	H-003	Low risk	1213010200	2010-01-19
CKMB	H-004	Low risk	1213010200	2010-01-19
Myoglobin	H-005	Low risk	1270130200	2010-01-19
Myoglobin	H-006	Low risk	1270130200	2010-01-19
<u>Panel of AMI</u> 3 in 1 combo	H-007	Low risk	1213019000	2010-01-19
<u>Panel of AMI</u> 3 in 1 combo	H-008	Low risk	1213019000	2010-01-19
CRP	H-009	Low risk	1213019000	2010-01-19
CRP	H-010	Low risk	1213019000	2010-01-19
BNP-Single	H-011	Low risk	1213010100	2010-01-19
BNP+1- 3 line	H-012	Low risk	1213010100	2010-01-19
BNP+2- 4 line	H-013	Low risk	1213010100	2010-01-19
α-FP	C-005	Low risk	1270039000	2010-01-19
α-FP	C-006	Low risk	1270039000	2010-01-19
α-FP	C-007	Low risk	1270039000	2010-01-19
CEA	C-008	Low risk	1203013100	2010-01-19
CEA	C-009	Low risk	1203013100	2010-01-19
CEA	C-010	Low risk	1203013100	2010-01-19
CEA	C-011	Low risk	1203013100	2010-01-19
HCCα-FP	C-012	Low risk	1270039000	2010-01-19
HCCα-FP	C-013	Low risk	1270039000	2010-01-19

Device name	Type/ model/ref number	Risk class	EDMS-code	First date of CE-marking
HCCaFP	C-014	Low risk	1270039000	2010-01-19
HCCaFP	C-015	Low risk	1270039000	2010-01-19
FOB	C-016	Low risk	1270039000	2010-01-19
FOB	C-017	Low risk	1270039000	2010-01-19
FOB	C-018	Low risk	1270039000	2010-01-19
Micro-Albumin	C-020	Low risk	1102010100	2010-01-19
Down's hCG	F-001	Low risk	1270050200	2010-01-19
Down's α -FP	F-003	Low risk	1210010100	2010-01-19
Down's hCG	F-001-1	Low risk	1270050200	2010-01-19
Down's hCG	F-003-3	Low risk	1270050200	2010-01-19
hCG	F-007	Low risk	1270050200	2010-01-19
hCG	F-008	Low risk	1270050200	2010-01-19
hCG	F-009	Low risk	1270050200	2010-01-19
LH	F-012	Low risk	1270050400	2010-01-19
FSH	F-013	Low risk	1270050100	2010-01-19
NTD	F-014	Low risk	1205019000	2010-01-19
Abortion Inevitable Test	F-015	Low risk	1205019000	2010-01-19
NTD	F-014-B	Low risk	1205019000	2010-01-19
Abortion Inevitable Test	F-016	Low risk	1205019000	2010-01-19
H.Py-Ab Cassette	I-001	Low risk	1570010200	2010-01-19
H.Py-Ab Dip-stick	I-002	Low risk	1570010200	2010-01-19
H.Py Antigen Cassette	I-001-F	Low risk	1570010200	2010-01-19
H.Py Antigen Dip-stick	I-002-F	Low risk	1570010200	2010-01-19
Syphilis Cassette	I-025	Low risk	1570010500	2010-01-19
Syphilis Cassette	I-026	Low risk	1570010500	2010-01-19
Herpes Simplex 1 IgG	I-039	Low risk	1504030800	2010-01-19
Herpes Simplex 2 IgG	I-040	Low risk	1504031100	2010-01-19
Herpes Simplex 1 IgM	I-045	Low risk	1504030900	2010-01-19
Herpes Simplex 2 IgM	I-046	Low risk	1504031100	2010-01-19
Strep A Cassette	I-048-1	Low risk	1570010300	2010-01-19
Strep A Dip-stick	I-048-2	Low risk	1570010300	2010-01-19
Strep B Cassette	I-049-1	Low risk	1570010300	2010-01-19
Strep B Dip-stick	I-049-2	Low risk	1570010300	2010-01-19
Mumps IgG	I-052	Low risk	1504800800	2010-01-19
Mumps IgM	I-053	Low risk	1504800800	2010-01-19
Measles IgG	I-054	Low risk	1504400700	2010-01-19
Measles IgM	I-055	Low risk	1504400700	2010-01-19

Device name	Type/ model/ref number	Risk class	EDMS-code	First date of CE-marking
Varicella Zoster Virus IgG	I-056	Low risk	1504401000	2010-01-19
Varicella Zoster Virus IgM	I-057	Low risk	1504401000	2010-01-19
Respiratory Syncytial Virus IgG	I-058	Low risk	1504800500	2010-01-19
Respiratory Syncytial Virus IgM	I-059	Low risk	1504800500	2010-01-19
TB	I-060	Low risk	1570019000	2010-01-19
Dengue IgG	I-061	Low risk	1504401100	2010-01-19
Dengue IgM	I-062	Low risk	1504401100	2010-01-19
Dengue IgG/IgM- Combo	I-062-C	Low risk	1504401100	2010-01-19
Chagas IgG	I-063	Low risk	1505100200	2010-01-19
Chagas IgM	I-064	Low risk	1505100200	2010-01-19
EBV IgG	I-067	Low risk	1504044000	2010-01-19
EBV IgM	I-068	Low risk	1504044000	2010-01-19
Malaria – p.f	I-069	Low risk	1570019000	2010-01-19
Malaria p.v	I-070	Low risk	1570019000	2010-01-19
Malaria p.f/p.v Combo	I-071	Low risk	1570019000	2010-01-19
Influenza A-H1N1 Virus	I-075G	Low risk	1504800400	2010-01-19
Influenza A-H1N1 Virus	I-075S	Low risk	1504800400	2010-01-19
Neo-TSH Cassette	T-001	Low risk	1204010300	2010-01-19
Neo-TSH Dip-stick	T-002	Low risk	1204010300	2010-01-19
Neo-TSH Cassette	T-003	Low risk	1204010300	2010-01-19
TSH Cassette	T-004	Low risk	1204011100	2010-01-19
TSH Dip-stick	T-005	Low risk	1204011100	2010-01-19
TSH Cassette	T-006	Low risk	1204011100	2010-01-19
Semi-TSH Serum/plasma	T-007	Low risk	1204011100	2010-01-19
Semi-TSH Cassette	T-008	Low risk	1204011100	2010-01-19
Amphetamine	D-001	Low risk	1270090100	2010-01-19
Methamphetamine	D-002	Low risk	1209010200	2010-01-19
Cocaine	D-003	Low risk	1270090600	2010-01-19
Morphine	D-004	Low risk	1270090800	2010-01-19
THC (Marijuana)	D-005	Low risk	1270090500	2010-01-19
Benzodiazepines	D-006	Low risk	1270090400	2010-01-19
PCP	D-007	Low risk	1270090900	2010-01-19
Barbiturates	D-008	Low risk	1270090300	2010-01-19
MDMA (Estacy)	D-009	Low risk	1209019000	2010-01-19
Oxycodone(OXY)	D-010	Low risk	1209019000	2010-01-19

Device name	<u>Type/ model/ref number</u>	Risk class	EDMS-code	First date of CE-marking
TCA	D-011	Low risk	1209021500	2010-01-19
Methadone (MTD)	D-012	Low risk	1270090700	2010-01-19
Cotinine	D-013	Low risk	1209010800	2010-01-19
Human IgE Cassette	O-001	Low risk	1202010200	2010-01-19
Human IgE Dip-stick	O-002	Low risk	1202010200	2010-01-19
Human IgE Cassette	O-003	Low risk	1202010200	2010-01-19
Human Albumin Cassette	O-004	Low risk	1102010100	2010-01-19
Human Albumin Dip- stick	O-005	Low risk	1102010100	2010-01-19
Human Albumin Cassette	O-006	Low risk	1102010100	2010-01-19
QikTech™ instruments				
Rapid test reader/Digital Imaging Scanner	QikTech™ 2000	Low risk	2101100100	2010-01-19
ELISA Reader	QikTech™ 1999	Low risk	2102100100	2010-01-19
Luminometer	QikTech™ 2010	Low risk	2102100100	2010-01-19