

DECLARATION OF CONFORMITY

1) Manufacturer (Name, department): **Calbiotech, Inc.**

Address: **10461 Austin Drive, SPRING VALLEY, CA 91978, USA.**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS Tel.: +31 (0)6 516 536 26;
or as: CEpartner4U, 3951DB; 13. NL tel: +31 (0)6 – 516.536.26)

3) Product(s) (name, type or model/batch number, etc.):

- **ELISA Test Kits**
- **Chemiluminescence Test Kits (LumELISA)**
see appendix

4) The product(s) described above is in conformity with:

<u>Title</u>	<u>Document No.</u>	<u>Date of issue</u>
<i>In vitro</i> Diagnostic Medical Devices Directive	98/79/EC As amended (EC) No 1882/2003	1998-10-27 2003-09-29

5) The product(s) described in the attached appendix is in conformity to the current European IVDD Directive and the associated quality management system is in compliance to ISO 13485:2003 (Certificate # UQA 0113239).

6) Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure for CE marking: Medical Device Directive, Annex III

Spring Valley, USA; 2009-03-19 -----

Mr. David Barka, Director of Quality System and IVD compliance

(Place & date of issue (yyyy-mm-dd))

(Name; function and signature of manufacturer)

Maarn, NL; 2009-03-19 -----

Rogier Nusselder; Consultant, CEpartner4U BV

(Place & date of issue (yyyy-mm-dd))

(name; function and signature of authorized representative)

Appendix

Date: 2009-03-19

List of devices.

ELISA TESTS				
Device types	Catalog #	EDMS code	First CE-mark (date)	Remark
Endocrine Markers				
ACTH	AC018T	1206040100	2005-08-12	
ACTH ELISA (Mouse/Rat)	AC018T-100	1206040100	2009-03-19	
Cortisol	CO078S	1206020400	2005-08-12	
Cortisol Saliva	CO116S	1206020400	2007-06-07	
Cortisol ELISA (Sheep)	CO116S-400	1206020400	2009-03-19	
C-Peptide	CP097D	1206010100	2005-08-12	
C-Reactive Protein	CR-016C	1211010900	2005-08-12	
DHEA-S	DH079S	1205010200	2005-08-12	
Estradiol	ES071S	1205010300	2005-08-12	
Free Estriol	EF068F	1205020300	2005-08-12	
Free Testosterone	FT014S	1205011000	2005-08-12	
Free Thyroxine (FT4)	FT4074	1204010200	2009-03-19	
Free Triiodothyronine (FT3)	FT3075	1204010100	2009-03-19	
FSH	FS046F	1205010400	2005-08-12	
Growth Hormone	HG048H	1206040200	2005-08-12	
hCG	HC047F	1205020500	2005-08-12	
IgE	IE066A	1202010200	2005-08-12	
Insulin	IS098D	1206010300	2005-08-12	
Insulin (Saliva)	IS121D	1206010300	2007-06-07	
LH	LH049F	1205010500	2005-08-12	
Progesterone	PG072S	1205010600	2005-08-12	
Progesterone for Saliva	PG119S	1205010600	2007-06-07	
Pro-insulin	PI099D	1206010800	2005-08-12	
Prolactin	PR063F	1205010800	2005-08-12	
Prolactin (Mouse/Rat)	PR063F-100	1205010800	2009-03-19	
PTH	PT019T	1206031300	2005-08-12	
Testosterone	TE080S	1205011000	2005-08-12	
Thyroxine (T4)	T4105T	1204010700	2007-06-07	

ELISA TESTS

Device types	Catalog #	EDMS code	First CE-mark (date)	Remark
Thyroxine (T4) ELISA (Mouse/Rat)	T4105T-100	1204010700	2009-03-19	
Triiodothyronine (T3)	T3104T	1204010500	2007-06-07	
Triiodothyronine (T3) ELISA (Mouse/Rat)	T3104T-100	1204010500	2009-03-19	
TSH	TS045T	1204011100	2005-08-12	
Cancer Markers				
Beta 2 Microglobulin	BM010T	1203900200	2005-08-12	
AFP	AF064T	1203900100	2005-08-12	
CA 15-3	C19012T	1203010200	2005-08-12	
CA 19-9	C15013T	1203010300	2005-08-12	
CA 125	C25011T	1203010600	2005-08-12	
CEA	CE062T	1203013100	2005-08-12	
Ferritin	FR065F	1207010200	2005-08-12	
Free-beta hCG	FB157E	1203909000	2009-03-19	
Cardiac Markers				
CKMB	CK154C	1213010200	2009-03-19	
FABP	FA155C	1213010300	2009-03-19	
MPO	MP156A	1210900900	2009-03-19	
Myoglobin	MG017C	1213010500	2005-08-12	
Troponin I	TI015C	1213010700	2005-08-12	
Drug of Abuse				
Cotinine	CO096D	1209010800	2005-08-12	
Cotinine (Mouse/Rat)	CO096D	1209010800	2005-08-12	
Fentanyl	FE087D	1209019000	2005-08-12	
Morphine (Canine)	MO091D-300	1209011200	2005-08-12	
Autoimmune Disorders				
ANA Screen IgG	AN033G	1210900100	2005-08-12	
Cardiolipin IgA	CA035A	1210900100	2005-08-12	
Cardiolipin IgG	CA034G	1210900100	2005-08-12	
Cardiolipin IgM	CA036M	1210900100	2005-08-12	
Cardiolipin Total Ab	CA077T	1210900100	2005-08-12	
dsDNA IgG	DD037G	1210010500	2005-08-12	
Mitochondrial (MA) Ab	MT073G	1210900200	2005-08-12	
RNP/Sm IgG	RN038G	1210011400	2005-08-12	

ELISA TESTS

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Scl-70	SC043G	1210011000	2005-08-12	
Sm IgG	SM039G	1210011100	2005-08-12	
SSA IgG	SA040G	1210011200	2005-08-12	
SSB IgG	SB041G	1210011300	2005-08-12	
Thyroglobulin (TG) Ab	TG070T	1210030400	2005-08-12	
Thyroid Peroxidase (TPO) IgG	TP069G	1210030100	2005-08-12	
Infectious Diseases				
Anthrax IgG	AP024G	1501909000	2005-08-12	
Brucella IgG	BA052G	1501900100	2005-08-12	
Brucella IgM	BA053M	1501900100	2005-08-12	
Dengue Virus IgG	DE050G	1504801100	2005-08-12	
Dengue Virus IgM	DE051M	1504801100	2005-08-12	
EBV-VCA IgA	EV011A	1504040400	2005-08-12	
EBV-VCA IgG	EV010G	1504040400	2005-08-12	
EBV-VCA IgM	EV012M	1504040400	2005-08-12	
H. pylori IgA	HP014A	1501040300	2005-08-12	
H. pylori IgG	HP013G	1501040300	2005-08-12	
H. pylori IgM	HP015M	1501040300	2005-08-12	
HSV-1 IgG	H1029G	1504030800	2005-08-12	
HSV-1 IgM	H1030M	1504030900	2005-08-12	
HSV -2 IgG	H2031G	1504031100	2005-08-12	
HSV-2 IgM	H2032M	1504031200	2005-08-12	
Measles IgG	MS018G	1504800700	2005-08-12	
Measles IgM	MS019M	1504800700	2005-08-12	
Mumps IgG	MP060G	1504800800	2005-08-12	
Mumps IgM	MP061M	1504800800	2005-08-12	
Mycoplasma IgG	MP020G	1501080300	2005-08-12	
Mycoplasma IgM	MP021M	1501080300	2005-08-12	
Salmonella IgG	ST093G	1501100300	2005-08-12	
Salmonella IgM	ST084M	1501100300	2005-08-12	
Treponema pallidum IgG	TP076G	1501030500	2005-08-12	
Treponema pallidum IgM	TP089M	1501030600	2005-08-12	
Treponema pallidum Total	TP094T	1501030300	2005-08-12	
VZV IgG	VZ081G	1504801000	2005-08-12	
VZV IgM	VZ082M	1504801000	2005-08-12	

Chemilumiscence TESTS (LumELISA)

Device types	Catalog #	EDMS code	First CE-mark (date)	Remark
Fertility Markers				
ACTH Ultra Sensitive lumELISA	AC562T	1206040100	2009-03-19	
ACTH Ultra Sensitive lumELISA (Mouse/Rat)	AC562T-100	1206040100	2009-03-19	
Estradiol Ultra Sensitive lumELISA	ES561S	1205010300	2009-03-19	
FSH Ultra Sensitive lumELISA	FS551F	1205010400	2005-08-12	
LH Ultra Sensitive lumELISA	LH550F	1205010500	2005-08-12	