

Each product group: ELISA, DECLARATION OF CONFORMITY

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

Address: 1935 Cordell Ct., El Cajon, CA 92020, 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. www.cepartner4u.com)

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

- ELISA Test Kits

see appendix

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

<u>Title</u>	<u>Document No.</u>
<i>In vitro</i> Diagnostic Medical Devices Directive	98/79/EC

5) **Additional information** (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

El Cajon, USA;

2021-11-24

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



Sheila Mattera, Director of Quality System and IVD compliance

(name; function and signature of manufacturer)

Appendix

Date: 2021-11-24

Registration / notification in:

√ Austria	√ Denmark	√ Greece	√ Latvia	√ Netherlands	√ Slovakia	√ Turkey
√ Belgium	√ Estonia	√ Hungary	√ Liechtenstein	√ Norway	√ Slovenia	√ United Kingdom
√ Bulgaria	√ Finland	√ Iceland	√ Lithuania	√ Poland	√ Spain	
√ Cyprus	√ France	√ Ireland	√ Luxembourg	√ Portugal	√ Sweden	
√ Czech Republic	√ Germany	√ Italy	√ Malta	√ Romania	√ Switzerland	

List of devices

ELISA TESTS						
Device types	Catalog #	Risk Class	GMDN	First CE-Mark (Date)	Final CE-Mark (Date)	Format
Allergy Marker						
IgE ELISA	IME00024	Low	17371	02/23/2018		ELISA
Ferritin ELISA	IME00025	Low	17342	02/23/2018		ELISA
Folate ELISA	IME00026	Low	30378	02/23/2018		ELISA
Autoimmune Disorders						
ANA IgG ELISA	IME00065	Low	17269	02/23/2018		ELISA
Cardiolipin IgA ELISA	IME00066	Low	30475	02/23/2018		ELISA
Cardiolipin IgG ELISA	IME00067	Low	30475	02/23/2018		ELISA
Cardiolipin IgM ELISA	IME00068	Low	30475	02/23/2018		ELISA
Cardiolipin Total Ab ELISA	IME00069	Low	30475	02/23/2018		ELISA
dsDNA IgG ELISA	IME00070	Low	17264	02/23/2018		ELISA
Mitochondrial (MA) Ab ELISA	IME00071	Low	17267	02/23/2018		ELISA
RNP/Sm IgG ELISA	IME00072	Low	30464	02/23/2018		ELISA
Scl-70 IgG ELISA	IME00073	Low	30463	02/23/2018		ELISA
Sm IgG ELISA	IME00074	Low	17276	02/23/2018		ELISA
SSA IgG ELISA	IME00075	Low	43427	02/23/2018		ELISA
SSB IgG ELISA	IME00076	Low	42899	02/23/2018		ELISA
Thyroglobulin (TG) IgG ELISA	IME00077	Low	17280	02/23/2018		ELISA
Thyroid Peroxidase (TPO) IgG ELISA	IME00078	Low	17282	02/23/2018		ELISA
Bone Metabolism Markers						
25(OH) Vitamin D ELISA	IME00029	Low	30350	02/23/2018		ELISA
Bio Intact PTH ELISA	IME00031	Low	30353	02/23/2018		ELISA
PTH ELISA	IME00030	Low	30353	02/23/2018		ELISA
Cancer Markers						
AFP ELISA	IME00037	Low	17259	02/23/2018		ELISA
Beta 2 Microglobulin ELISA	IME00036	Low	30296	02/23/2018		ELISA
CA 15-3 ELISA	IME00038	Low	30279	02/23/2018		ELISA
CA-125 ELISA	IME00040	Low	30283	02/23/2018		ELISA
CA 19-9 ELISA	IME00039	Low	30280	02/23/2018		ELISA
CEA ELISA	IME00041	Low	17293	02/23/2018		ELISA
Chromogranin A ELISA	IME00042	Low	30289	02/23/2018		ELISA
HE4 ELISA	IME00046	Low		02/23/2018		ELISA
Free Beta-hCG ELISA	IME00045	Low	38246	02/23/2018		ELISA
Cardiac Markers						
Myoglobin ELISA	IME00050	Low	17314	02/23/2018		ELISA
Troponin I ELISA	IME00051	Low	30266	02/23/2018		ELISA

CKMB ELISA	IME00047	Low	30507	02/23/2018		ELISA
Fertility Markers						
FSH ELISA	IME00006	Low	30322	02/23/2018		ELISA
hCG ELISA	IME00007	Low	30332	02/23/2018		ELISA
LH ELISA	IME00008	Low	38246	02/23/2018		ELISA
Prolactin ELISA	IME00009	Low	30325	02/23/2018		ELISA
AMH ELISA	IME00127	Low		04/16/2019		ELISA
Diabetes Markers						
C-Peptide ELISA	IME00021	Low	30336	02/23/2018		ELISA
Insulin ELISA	IME00022	Low	30338	02/23/2018		ELISA
Drug of Abuse						
Cotinine ELISA	IME00056	Low	30429	02/23/2018		ELISA
Growth Markers						
hGH ELISA	IME00028	Low	30358	02/23/2018		ELISA
Infectious Disease						
Brucella IgG ELISA	IME00080	Low	17289	02/23/2018		ELISA
Brucella IgM ELISA	IME00081	Low	17289	02/23/2018		ELISA
COVID-19 IgG ELISA	IME00136	Low		04-14-2020		ELISA
COVID-19 IgM ELISA	IME00137	Low		04-28-2020		ELISA
COVID-19 IgG Dried Blood Spot	IME00138	Low		09-28-2020		ELISA
Dengue Virus IgG ELISA	IME00090	Low	39519	02/23/2018		ELISA
Dengue Virus IgM ELISA	IME00091	Low	39519	02/23/2018		ELISA
EBV-VCA IgA ELISA	IME00092	Low	33971	02/23/2018		ELISA
1 EBV-VCA IgG ELISA	IME00093	Low	17339	02/23/2018		ELISA
2 EBV-VCA IgM ELISA	IME00094	Low	17339	02/23/2018		ELISA
H. Pylori IgA ELISA	IME00095	Low	30691	02/23/2018		ELISA
H. Pylori IgG ELISA	IME00096	Low	30691	02/23/2018		ELISA
H. Pylori IgM ELISA	IME00097	Low	30691	02/23/2018		ELISA
HSV-1 IgG ELISA	IME00098	Low	30805	02/23/2018		ELISA
HSV-1 IgM ELISA	IME00099	Low	30806	02/23/2018		ELISA
HSV-2 IgG ELISA	IME00100	Low	38875	02/23/2018		ELISA
HSV-2 IgM ELISA	IME00101	Low	38875	02/23/2018		ELISA
Measles IgG ELISA	IME00102	Low	44019	02/23/2018		ELISA
Measles IgM ELISA	IME00103	Low	44019	02/23/2018		ELISA
Mumps IgG ELISA	IME00104	Low	17309	02/23/2018		ELISA
Mumps IgM ELISA	IME00105	Low	17309	02/23/2018		ELISA
Mycoplasma IgG ELISA	IME00106	Low	17311	02/23/2018		ELISA
Mycoplasma IgM ELISA	IME00107	Low	17311	02/23/2018		ELISA
Salmonella IgG ELISA	IME00110	Low	17384	02/23/2018		ELISA
Salmonella IgM ELISA	IME00111	Low	17384	02/23/2018		ELISA
Treponema pallidum IgG ELISA	IME00115	Low	30688	02/23/2018		ELISA
Treponema pallidum IgM ELISA	IME00116	Low	40200	02/23/2018		ELISA
VZV IgG ELISA	IME00118	Low	33861	02/23/2018		ELISA
VZV IgM ELISA	IME00119	Low	33861	02/23/2018		ELISA
Inflammatory Markers						
Alpha 1-Antichymotrypsin (ACT) ELISA	IME00032	Low	17257	02/23/2018		ELISA
CRP ELISA	IME00034	Low	17290	02/23/2018		ELISA
Lysozyme ELISA	IME00033	Low	38547	02/23/2018		ELISA
Secretory IgA ELISA	IME00035	Low	31446	02/23/2018		ELISA
Anemia Markers						
Vitamin B12 ELISA	IME00027	Low	30384	02/23/2018		ELISA
Steroid Markers						
ACTH ELISA	IME00010	Low	30357	02/23/2018		ELISA
Androstenedione ELISA	IME00011	Low	30319	02/23/2018		ELISA
DHEA-S ELISA	IME00013	Low	30320	02/23/2018		ELISA

Estriol, Free ELISA	IME00015	Low	30329	02/23/2018		ELISA
Progesterone ELISA	IME00017	Low	30325	02/23/2018		ELISA
17(OH) Progesterone ELISA	IME00018	Low	30325	02/23/2018		ELISA
Estradiol ELISA	IME00014	Low	30321	02/23/2018		ELISA
Estrogens, Total ELISA	IME00016	Low	33293	02/23/2018		ELISA
Testosterone, Free ELISA	IME00020	Low	30327	02/23/2018		ELISA
Testosterone, Total ELISA	IME00019	Low	30327	02/23/2018		ELISA
Thyroid Markers						ELISA
Thyroxine (T4) ELISA	IME00001	Low	30314	02/23/2018		ELISA
Thyroxine, Free (FT4) ELISA	IME00002	Low	30309	02/23/2018		ELISA
Triiodothyronine (T3) ELISA	IME00003	Low	30312	02/23/2018		ELISA
Triiodothyronine, Free (FT3) ELISA	IME00004	Low	30308	02/23/2018		ELISA
TSH ELISA	IME00005	Low	30318	02/23/2018		ELISA
T3 Uptake	IME00126	Low		04/16/2019		ELISA

NEONATAL TESTS (ELISA)						
Device types	Catalog #	Risk Class	GMDN	First CE-Mark (Date)	Final CE-Mark (Date)	Format
Neonatal TSH ELISA	IME00121	Low	30318	02/23/2018		ELISA
Neonatal T4 ELISA	IME00120	Low	30314	02/23/2018		ELISA
MSUD Neonatal ELISA	IME00124	Low		02/23/2018		ELISA
Neonatal 17A-OH Progesterone ELISA	IME00125	Low	30325	02/23/2018		ELISA
Neonatal Galactose ELISA	IME00123	Low	30166	02/23/2018		ELISA

Reagents						
Device types	Catalog #	Risk Class	GMDN	First CE-Mark (Date)	Final CE-Mark (Date)	Format
Wash Buffer Concentrate, 20X	IME00139	Low		08-17-2020		

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