



Ministry of Health, Welfare and Sport  
 CIBG  
 Box 16114  
 2500 BC The Hague  
 THE NETHERLANDS



## STATEMENT

The undersigned herewith declares that according to the Decree on In-Vitro Diagnostics, which is based on the European Directive 98/79/EC concerning in-vitro diagnostic medical devices,

Cepartner4u B.V.  
 Esdoornlaan 13  
 3951 DB Maarn  
 THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Calbiotech Inc.  
 1935 Cordell Ct.  
 El Cajon CA 92020  
 UNITED STATES OF AMERICA

is authorised to manufacture and/or supply the medical device/devices mentioned below:

### See product list

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to non-EU Member States. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of VIETNAM .

This statement is valid until May 26, 2022.

The Hague, July 16, 2021

On behalf of the Minister for Medical Care and Sport  
 Farmatec | CIBG

  
 Dr. M.J. van de Velde  
 Head of Department



Ministerie van Buitenlandse Zaken

Our reference: 20214478  
 Certificate number: 32849

Gezien voor legalisatie van de handtekening  
 The undersigned legalises the signature

**M.J. van de Velde**

van/of

De minister van Buitenlandse Zaken, voor deze,  
 For the minister of Foreign Affairs,



01-2021-0001



**CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ**  
**CONSULAR AUTHENTICATION**

1. Quốc gia/ *Country*. **VIỆT NAM**  
*Giấy tờ, tài liệu này / This public document*
2. do ông/bà **L. STUIJFZAND** ký  
*has been signed by*
3. với chức danh **Viên chức BNG Hà Lan**  
*acting in the capacity of*
4. và con dấu của: **Bộ Ngoại giao Hà Lan**  
*bears the seal/stamp of*  
được chứng nhận/hợp pháp hóa lãnh sự / *certified*
5. tại/at: **The Hague** 6. Ngày/the: **04/08 / 2021**
7. Cơ quan cấp/ by: **Đại sứ quán Việt Nam tại Hà Lan**
8. Số/ No: **142** /2021


**TL. Đại sứ**  
**Tham tán**



**Nguyễn Hoàng Hải**

**ELISA TESTS**

Device types	Catalog #	Risk Class	GMDN	First CE-Mark (Date)	Final CE-Mark (Date)	Format
<b>Allergy Marker</b>						
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
<b>Autoimmune Disorders</b>						
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
<b>Bone Metabolism Markers</b>						
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
<b>Cancer Markers</b>						
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
<b>Cardiac Markers</b>						
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
<b>Fertility Markers</b>						
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
<b>Diabetes Markers</b>						
C-Peptide ELISA	IME00021	Low	30336	02/23/2018		ELISA
Insulin ELISA	IME00022	Low	30338	02/23/2018		ELISA
Pro Insulin ELISA	IME00023	Low	42852	02/23/2018		ELISA
<b>Drug of Abuse</b>						
Amphetamine ELISA	IME00052	Low	30516	02/23/2018		ELISA
Barbiturates ELISA	IME00053	Low	30517	02/23/2018		ELISA

  
 D. M. de Velde  
 Minister van Volksgezondheid, Welzijn en Sport  
 Ministry of Health, Welfare and Sport

Cannabinoids ELISA	IME00054	Low	30519	02/23/2018		ELISA
Cocaine Metabolite ELISA	IME00055	Low	30520	02/23/2018		ELISA
Cotinine ELISA	IME00056	Low	30429	02/23/2018		ELISA
Fentanyl ELISA	IME00057	Low	31619	02/23/2018		ELISA
Flunitrazepam ELISA	IME00058	Low	31619	02/23/2018		ELISA
LSD ELISA	IME00059	Low	31619	02/23/2018		ELISA
Methamphetamine ELISA	IME00060	Low	39070	02/23/2018		ELISA
Morphine Specific ELISA	IME00061	Low	31619	02/23/2018		ELISA
Opiates ELISA	IME00062	Low	30522	02/23/2018		ELISA
PCP ELISA	IME00063	Low	30523	02/23/2018		ELISA
Tricyclics ELISA	IME00064	Low	30524	02/23/2018		ELISA
<b>Growth Markers</b>						
hGH ELISA	IME00028	Low	30358	02/23/2018		ELISA
<b>Infectious Disease</b>						
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
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
Treponema pallidum Total ELISA	IME00117	Low	17393	02/23/2018		ELISA
VZV IgG ELISA	IME00118	Low	33861	02/23/2018		ELISA
VZV IgM ELISA	IME00119	Low	33861	02/23/2018		ELISA
<b>Inflammatory Markers</b>						
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
<b>Anemia Markers</b>						
Vitamin B12 ELISA	IME00027	Low	30384	02/23/2018		ELISA
<b>Steroid Markers</b>						
ACTH ELISA	IME00010	Low	30357	02/23/2018		ELISA
Androstenedione ELISA	IME00011	Low	30319	02/23/2018		ELISA
Cortisol ELISA	IME00012	Low	43259	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
<b>Thyroid Markers</b>						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

<b>NEONATAL TESTS (ELISA)</b>						
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