

Ministry of Health, Welfare and Sport  
CIBG  
P.O. 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,

SUNGO Europe B.V.  
Olympisch Stadion 24  
1076 DE Amsterdam  
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Wuhan Life Origin Biotech Joint Stock Co., Ltd  
Floor 1st. 2nd and 3rd , Wuhan Hi-Tech Medical Device Park B11  
No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone  
Wuhan, Hubei  
CHINA

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

**SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)**  
**SARS-CoV-2 Nucleic Acid Dual-Detection Kit(Real-Time PCR Method)**

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 **MEXICO**.

This statement is valid until April 26, 2025.

The Hague, June 15, 2020

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

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


Our reference: 20201694  
Certificate number: 27622

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