

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



FREE SALES CERTIFICATE

The undersigned herewith declares that, according to the Decree on In-Vitro Diagnostics, which is based on Regulation (EU) 2017/746¹,

SUNGO Europe B.V.
Fascinatio Boulevard 522 (Unit 1.7)
2909 VA Capelle Aan Den IJssel
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

BioTeke Corporation (Wuxi) Co., Ltd
Zone A, Floor 4, No.1719-5, Huishan Avenue, Huishan Economic Development Zone,
Wuxi, Jiangsu 214174
CHINA

which has its authorized address in the Netherlands and is authorized to manufacture and/or supply the medical device/devices mentioned below:

See product list

This device/these devices, that has/have a CE-marking, may be placed on the Dutch market and on the markets of the other Member States of the European Union. This Free Sales Certificate may only be used for export outside the European Union.

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

This Free Sales Certificate is valid up to and including March 22, 2028.

The Hague, April 24, 2023

On behalf of State Secretary for Health, Welfare and Sport
Farmatec | CIBG



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



Our reference: 20231195
Certificate number: 40340

¹ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.



Ministerie van Buitenlandse Zaken

Gezien voor legalisatie van de handtekening
The undersigned legalises the signature

van/of **M.J. van de Velde**

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

02 mei 2023 - P.C. Swinkels

MLD687931



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 **P.C. SWINKELS** 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: **8 / 5 / 2023**
7. Cơ quan cấp/ by: **Đại sứ quán Việt Nam tại Hà Lan**
8. Số/ No: **486a** /2023

KT. Đại sứ
Tham tán công sứ



Lê Tuấn Anh

No.	Product Name	Models
01	Nucleic Acid Extraction Kit	DP4611, DP4612, DP4613, AU17011, AU17012, AU18012, AU18012-96, AU1811, AU1812, AU52111
02	Disposable Virus Sampling Swab Kits	ZK1000-1, ZK1500-1, ZK1000-5, ZK1500-2, ZK1500-3, ZK1500-4, ZK1500-5
03	Disposable Virus Sampling Swab Kits	ST7001-0, ST7001-1, ST7001-2, ST8001-0, ST8001-1, ST8001-2, ST9001-0, ST9001-1, ST9001-2
04	Automated Nucleic Acid Extraction System	AU1001, AU1001S, AU1001-96
05	Fast Real-time Fluorescence PCR Analyzer	BTK-8, BTK-1
06	Automated Sample Transfer Processing System	BF4096
07	Pipette	PT10, PT50, PT100, PT200, PT1000, PT5000, PTE10, PTE50, PTE100, PTE200, PTE300


 Dr. M.J. van de Ven
