CE Notification Confirmation

This is to confirm that, according to the council directive 98/79/EC, SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

Shandong Chengwu Medical Products Factory
Southern End of Quancheng Road, Chengwu County,
274200 Heze City, Shandong Province, P.R.China.

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the In Vitro Diagnostic Medical Device (IVDD), as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 98/79/EC.

According to 98/79/EC, the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's In Vitro Diagnostic Medical Device and has allocated registration number.

Disposable Virus Specimen Collection Tube

Not in List A and List B according to Annex II of 98/79/EC

GMDN CODE : 63232

CIBG Number: NL-CA002-2020-50479

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

Reference Number: EUCAN00195
Issue date: May, 06, 2020

For and on behalf of
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Authorized Signature
sed for the EU Representative Signature

SUNGO Europe B.V.
Olympisch Stadion 24,1076DE
Amsterdam, Netherlands
ec.rep@sungogroup.com

Digitally Signed by Ceaicovschi Tudor
Date: 2022.06.29 11:09:49 EEST
Reason: MoldSign Signature
Location: Moldova

REGISTRATION NO. 04720Q10000336

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Chengwu Medical Products Factory

Registered Address: Southern End of Quancheng Road,Chengwu County,274200 Heze City,Shandong Province,P.R.China

Manufacturing Address: Southern End of Quancheng Road,Chengwu County

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The development,production and service of disposable virus specimen collection tube.

Date of issue: July 13,2020

Date of expiry: July 12,2023

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

EU Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: SHANDONG CHENGWU MEDICAL PRODUCTS FACTORY
Southern end of Huxin road, Chengwu county, Heze city, Shandong province, P. R. CHINA.
Fax: +86-530-8623064

European Representative: Sungo Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
ec.rep@sungogroup.com

Product Name: Swab
GMDN CODE: 57940
Classification: General, (IVDD, Article9(1)) NOT BE PART OF LIST A & B OF ANNEX II
Conformity Assessment Route: ANNEX III (EXCEPT POINT 6) OF IVDD 98/79/EC

We herewith declare that the above mentioned product meets the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the promise of the manufacturer.
We, as manufacturer, are exclusively responsible for this Doc.

Standards Applied:

EN ISO 15223-1:2016	EN 1041:2008+A1:2003	EN ISO 13485:2016
EN ISO 14971:2012	EN ISO 18113-1:2011	

Place, Date of Issue: Chengwu, Shandong, 2020-03-01

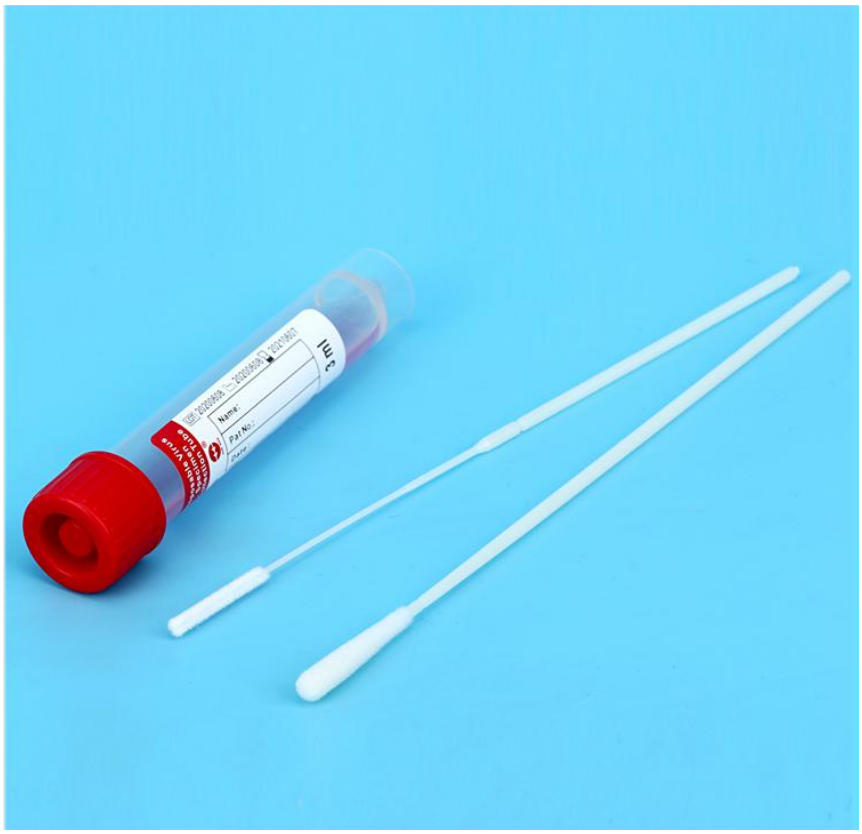
Signature:

Name: 王继存

Position: General Manager

CE

SHANDONG CHENGWU MEDICAL PRODUCTS FACTORY



Product Name：Disposable Virus Specimen Collection Tube
Shelf Life：12 months
Store Under：Room Temperature 4-25℃

Product Description:
Virus collection kit is used for collection,transport,maintenance and long term freeze storage of Viruses, such as COVID-19 Virus,Influenza,including H1N1,Chlamydia,Mycoplasma and Ureaplasma specimens.The Virus sampling tube swab kit can be conveniently stored at room temperature.

Sampling tube:
The tube body and tube cap are Sterilized by Gamma Radiation , Non heat source, DNAse and RNAse free. To ensure that the sampling tube itself will not have a toxic effect on the sample. The tube body and cap are made of high-quality medical grade polypropylene material, which is transparent and clean, without deformation at high temperature and high pressure (120 ℃ 15min), and does not become brittle at low temperature (-80 ℃)

Sample Requirements

The collected flock swab samples should be transported at 2°C-8°C and submitted for inspection immediately. Sample transport and storage time should be no later than 72h.

User Manual

1. Mark the sample information on the label before sampling.
2. Collect the specimen with the swab.
a. Nasal swab: gently insert the swab into the nasal cavity for sampling, use another swab to collect another nasal sample in the same way.
b. Throat swab: collect the throat sample.
3. Put the swab into the transport tube contains virus transport medium after sampling.
4. Snap the swab at the break point into the transport tube and screw the cap tightly.
5. It is better o transport the collected samples to the laboratory with ice packs.

Pay Attention

1. When collecting and handling specimens, gloves, protective clothing, goggles and other personal protective equipment shall be worn to avoid splashing, leakage and exposure of potential pathogens.
2. All biohazardous specimens and devices shall be disposed of in accordance with the relevant regulations and procedures and discarded in the designated collection containers.
4. After use, the waste shall be disposed according to the regulations of the hospital or the environmental protection department.
5. Read Instructions for Use on this packing carefully before use,and use it within the validity period.
6. Warming and prevention: it is forbidden to us when package damage, foreign matters, leakage,storage liquid turbidity and expiration date are found.

Kit include: 1pc 10ml sampling tube with 2ML VTM LIQUID or 3ML VTM LIQUID.
1pc Nasal flocked swab
1pc Oral flocked swab
Sterile blister pack.

Cat No.	Description	Qty/Case
611903	Virus collection kit with 2 swab,(1pc nasal swab+1pc oral swab)	300

Manufacturer

Shandong Chengwu Medical Products Factory
Add:Southern End of Huxin Road, Chengwu County, Heze City,Shandong Province P.R. China