



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

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

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

Authorized Signature
Only used for the EU Representative Signature

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

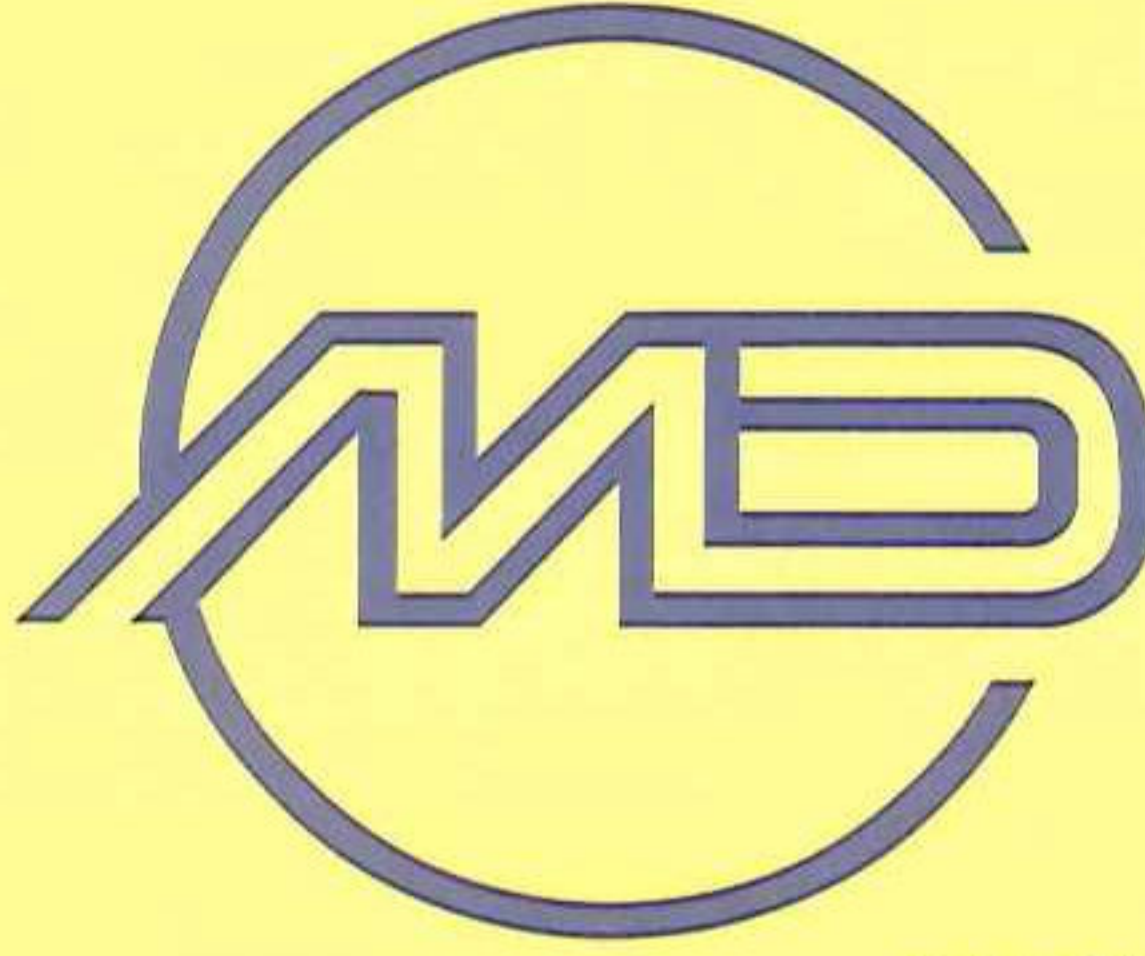
Place, Date of Issue: Chengwu, Shandong, 2020-03-01

Signature: 

Name: 

Position: General Manager





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