



EC Declaration of Conformity



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

Manufacturer:

Name: ShenZhen Cleanmo Technology Co. Ltd
Address: Room 608, 6/F., Building 13, Qinchengda, Zone 22, Xin'an Street, Bao'an District, Shenzhen city, Guangdong Province P.R.China

EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable Specimen Collection swab sticks
Type:

1. Nasopharyngeal Flocked Swab
CM-FS913
2. Oropharyngeal Flocked Swab
CM-FS915;CM-FS916,CM-NS915
3. DNA Flocked Swab
CM-FS913;CM-FS915;CM-FS916,CM-NS915,NFS913-LTP,NFS915-LTP, NFS916-LTP
4. Cervical Specimen Collection Flocked Swab
CM-FS919,CM-FS919D,CM-FS919K,CM-FS919V,CM-FS919T
5. Specimen Collection Foam Swab
CM-FS712;CM-FS740;CM-FS-707;CM-FS708
6. Specimen Collection Polyester Swab
CM-PS713;CM-PS761

Classification: IVDD Other

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

- EN13612: 2002
- EN ISO 14971:2012
- EN ISO 18113-1:2011
- EN ISO 18113-3:2011



On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



Signature:
Date: 2020/4/16

Authorized Signature (S)