



## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

### **SWORD XIANTAO DISPOSABLE PROTECTIVE PRODUCTS FACTORY**

**Liukou Industrial Zone, Xiantao Hubei, CHINA**

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA      SUNGO TECHNICAL SERVICE INC.  
Communications:      6050 W EASTWOOD AVE APT 201, CHICAGO,  
   ILLINOIS 60630, USA  
   Telephone: +1-855-957-7779 / E-mail: [sungo.group@yahoo.com](mailto:sungo.group@yahoo.com)

**Registration Number: 3009751960**

**Device Listing#: See annex**

*SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.*

*Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.*



Executive Director  
Issued: Mar. 20 2020  
Cert. No.: 2006US246558  
Expiration Date: Dec. 31 2020



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Annex to Cert. No.: 2006US246558

| Listing No | Code | Device Name   |
|------------|------|---|
| D152275    | FXO  | SUIT, SURGICAL<br>(Surgical Suit; Coverall)   |
| D152276    | FXP  | COVER, SHOE, OPERATING-ROOM<br>(Shoe Cover; Boot Cover, Disposale Slipper, Sleeve Cover)  |
| D152277    | FYF  | CAP, SURGICAL<br>(Surgical Cap; Cap/Disposable Cap/Non Woven Cap/Mob Cap/Clip Cap/Round Cap;Nurse Cap, Worker Cap, Balaclava Cap)   |
| D152278    | OEA  | NON-SURGICAL ISOLATION GOWN<br>(Gown; CPE Gown, Isolation Gown;PE Rain Coat)  |
| D152279    | LYU  | ACCESSORY, SURGICAL APPAREL<br>(Beard Cover;Mask With Fluidshield , Surgical Apparel Accessory;Mask Flat Isolation,Gloves; Surgical Apparel Accessory; Mask Flat Isolation 50/pcs box, 12boxes/carton; Mask Isolation Molded 50pcs/box, 20boxes/carton; Mask w/Fluidshield 50pcs/box, 4 box/carton) |
| D376143    | FYE  | DRESS, SURGICAL<br>(Dressing/Visitor Gown/Clothing;Visitor Gown/Visitor Coat, Lab Coat;Shorts;Briefs)   |
| D376144    | BWP  | SHOE AND SHOE COVER, CONDUCTIVE<br>(Shoe Cover)   |
| D376145    | KHA  | MASK, SCAVENGING<br>(Face Mask/Earloop Face Mask/Tie Face Mask)   |
| D376146    | FQM  | BANDAGE, ELASTIC<br>(Cohesive Bandage)  |
| D376147    | FOG  | HOOD, OXYGEN, INFANT<br>(Disposable Hood)   |
| D376149    | KME  | BEDDING, DISPOSABLE, MEDICAL<br>(Disposable Bed Sheet;Disposable Bed Cover; Disposable Pillow Cover)  |
| D376150    | FME  | Gown, examination<br>(Patient Gown)   |
| D376151    | IWO  | Apron, protective<br>(Apron, Bib)   |

END OF THE ANNEX